

4 Possible side effects

Like all medicines, Dianette can cause side effects, although not everybody gets them.

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Dianette, some women have reported feeling depressed whilst taking Dianette. In very rare cases this has been associated with thoughts of ending their lives. If you develop severe depression, you should stop Dianette as a precaution, and see your doctor straight away.

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue or throat.**
- A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- severe **pain in your stomach**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

➔ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Dianette.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- **feeling sick**
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**
- **venous blood clot**

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Dianette. If it continues, becomes heavy or starts again, contact your doctor
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Dianette for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps

- occurrence or deterioration of the movement disorder **chorea**
- **Crohn’s disease** or **ulcerative colitis**
- increase in blood pressure
- **conditions that may worsen during pregnancy or previous use of the Pill:**
 - **yellowing of the skin** (*jaundice*)
 - **persistent itching** (*pruritus*)
 - **kidney or liver problems**
 - **gall stones**
 - certain rare medical conditions such as **systemic lupus erythematosus**
 - **blister-like rash** (*herpes gestationis*) whilst pregnant
 - an inherited form of **deafness** (*otosclerosis*)
 - a personal or family history or a form of **sickle cell disease**
 - **swelling of body parts** (*hereditary angioedema*)
 - an inherited disease called **porphyria**
 - **cancer of the cervix**

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette. Also tell them if any existing conditions get worse while you are taking Dianette.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Dianette, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Dianette as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

➔ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you’ve been taking Dianette for a while
- carries on even after you’ve stopped taking Dianette.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Dianette

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C
- Do not use Dianette after the expiry date shown on the strip.
- If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do
- Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Dianette and who makes it

Your medicine

Each box of Dianette contains three strips of 21 yellow sugar-coated tablets. Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Dianette also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Weimar GmbH & Co. KG, Dobreinerstrasse 20, 99427 Weimar, Germany and is procured from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL Number: 15184/1298

Leaflet revision date: 05/05/16

Dianette is a registered trademark of Bayer Intellectual Property GmbH.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Dianette® Tablets (cyproterone acetate/ethinylestradiol) Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Your medicine is called Dianette Tablets, and will be referred to as Dianette throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Dianette is and what it is used for**
- 2 What you need to know before you take Dianette**

2.1 Before you take Dianette

When should you contact your doctor

Dianette and cancer

2.2 Make sure Dianette is OK for you

Dianette should not be taken by some women

Dianette can make some illnesses worse

Taking other medicines

Taking Dianette with food and drink

Pregnancy and breast-feeding

Driving and using machines

Dianette contains lactose

Dianette and sun-beds or sun-lamps

3 Taking Dianette

Duration of use

How to take it

Starting Dianette

A missed pill

A lost pill

If you are sick or have diarrhoea

Missed a period – could you be pregnant?

Taking more than one pill should not cause harm

When you want to get pregnant

4 Possible side effects

4.1 Serious side effects – see a doctor straight away

4.2 Less serious side effects

4.3 Bleeding between periods should not last long

5 How to store Dianette

6 What is in Dianette and who makes it

1 What Dianette is and what it is used for

Dianette contains an oestrogen and an anti-androgen. Dianette is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate. You should only take Dianette if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

If you are taking Dianette for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Dianette, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Dianette stops the androgens affecting your skin and reduces the amount of androgens produced.

Ref:1298/050516/1/F

Contraception

Dianette is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Dianette will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Dianette needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Dianette

2.1 Before you take Dianette

It’s important that you understand the benefits and risks of taking Dianette before you start taking it, or when deciding whether to carry on taking it. Although Dianette is suitable for most healthy women it isn’t suitable for everyone.

➔ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Dianette

- Your doctor will ask about you and your family’s medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you’re on Dianette

- You will need **regular check-ups** with your doctor, usually when you need another prescription of Dianette.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Dianette, because this type of medicine can affect the results of some tests.
- **If you’re going to have an operation**, make sure your doctor knows about it. You may need to stop taking Dianette about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Dianette again.
- **If you need to stop taking Dianette**, remember to use another contraceptive (e.g. condoms) if you are relying on Dianette for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in ‘Blood clots (Thrombosis)’ and in Section 4.

Dianette also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Dianette may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Dianette compared with women who do not take Dianette or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a ‘venous thrombosis’) can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman’s risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Dianette.

- Of 100,000 women who are **not taking Dianette, not on the Pill** and not pregnant, about **5 to 10** will have a blood clot in a year.
- Of 100,000 women who **take Dianette or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- **if you smoke.**

When using a hormonal contraceptive like Dianette you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

Page 1

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Dianette, as the treatment may have to be stopped. Your doctor may tell you to stop using Dianette several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Dianette again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke**.
 - **When using a hormonal contraceptive like Dianette you are strongly advised to stop smoking, especially if you are older than 35 years**;
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Dianette.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Dianette and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Dianette also provide the same protective effects. However, it also seems that taking Dianette slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Dianette. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Dianette or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Dianette, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Dianette users is small. For example:

- Of 10,000 women who have **never taken Dianette or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Dianette or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Dianette or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women **who take Dianette or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
- ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Dianette has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Dianette has also been linked with some forms of liver cancer in women who have taken it for a long time.
- ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Dianette.

2.2 Make sure Dianette is OK for you

Dianette should not be taken by some women

➔ **Tell your doctor** if you have any medical problems or illnesses.

Do not take Dianette Tell your doctor if any of the following conditions applies to you before starting to use Dianette. Your doctor may then advise you to use a different treatment:

- If you are using another hormonal **contraceptive**
- If you are **pregnant** or might be pregnant
- If you are **breast-feeding**
- If you have or have ever had **breast cancer**
- If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or **‘mini-stroke’** (transient ischaemic attack)
- If you have (or have ever had) a **heart attack** or **stroke**.
- If you have a condition that may increase the risk of a **blood clot** in your arteries. This applies to the following conditions:
 - **diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
- If you have problems with **blood clotting** (e.g. protein C deficiency)
- If you have (or have ever had) a **migraine, with visual disturbances**
- If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
- If you have ever had **liver tumours**
- If you are **allergic** (*hypersensitive*) to any of the ingredients in Dianette.
- ➔ **If you suffer from any of these**, or get them for the first time while taking Dianette, contact your doctor as soon as possible. Do not take Dianette. If needed, use another form of contraception.

Dianette can make some illnesses worse

Some of the conditions listed below can be made worse by taking Dianette. Or they may mean it is less suitable for you. You may still be able to take Dianette but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past

- If you are **overweight** (*obese*)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (chloasma) (see below ‘Dianette and sun-beds or sun-lamps’)
- If you have any **illness that worsened during pregnancy or previous use of the Pill or Dianette** (see section 4)

➔ **Tell your doctor if any apply to you**. Also tell them if you get any of these for the first time while taking Dianette, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Dianette, always tell your doctor, pharmacist or dentist that you’re taking Dianette. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Dianette for skin treatment, you must not take any other hormonal contraceptive at the same time. Some medicines can have an influence on the blood levels of Dianette and can stop it from working properly- for example

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics** (oral tetracyclines)
- **certain sedatives** (called *barbiturates*)
- **St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Dianette may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Dianette can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Dianette can also interfere with the results of some blood tests, so always tell your doctor that you are taking Dianette if you have a blood test

Taking Dianette with food and drink

There are no special instructions about food and drink while on Dianette.

Pregnancy and breast-feeding

Do not use Dianette if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Dianette.

Driving and using machines

Dianette has no known effect on the ability to drive or use machines.

Dianette contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Dianette.

Dianette and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Dianette. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3 Taking Dianette

Your doctor has chosen Dianette as a treatment for your acne or excessive hair growth on your face and body. However, Dianette also has a contraceptive effect, so it is important to follow the advice below if you are relying on Dianette for contraception.

If you are only using Dianette for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Dianette.

How to take it

Take Dianette every day for 21 days

Dianette comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Dianette as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight Start taking your next strip of Dianette after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time. As long as you take Dianette correctly, you will always start each new strip on the same day of the week.

Starting Dianette

New users or starting Dianette after a break

It is best to take your first Dianette pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Dianette from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Dianette the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Dianette.
 - **If you are taking a 28-day Pill:** start taking Dianette the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Dianette.
 - **If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Dianette on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.
- Starting Dianette after a miscarriage or abortion**
- If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Dianette straight away. This means that you will have contraceptive protection with your first pill.
- If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Dianette should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Dianette and for the first 7 days of pill taking.

Do not take Dianette if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.

- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.

- **Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Dianette**, follow the instructions in section 3.4 A lost pill, which describes how to take another pill. If you are still sick or have diarrhoea **more than 12 hours after taking Dianette**, see section 3.3, *A missed pill*.

➔ **Talk to your doctor if your stomach upset carries on or gets worse.**

He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly.

Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Dianette and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Dianette until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

Like all medicines, Dianette can cause side effects, although not everybody gets them.

- ➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Dianette, you should stop Dianette as a precaution, if you develop severe depression, and see your doctor straight away

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue or throat.**
- A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- **severe pain in your stomach**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

- ➔ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Dianette.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- feeling sick
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**
- **venous blood clot**

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Dianette. If it continues, becomes heavy or starts again, contact your doctor
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Dianette for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurrence or deterioration of the movement disorder **chorea**
- **Crohn's disease or ulcerative colitis**

- **conditions that may worsen during pregnancy or previous use of the Pill:**

- **yellowing of the skin** (*jaundice*)
- **persistent itching** (*pruritus*)
- **kidney or liver problems**
 - **gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- **blister-like rash** (*herpes gestationis*) whilst pregnant
- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- **swelling of body parts** (*hereditary angioedema*)
- an inherited disease called **porphyria**
- **cancer of the cervix**

- ➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette. Also tell them if any existing conditions get worse while you are taking Dianette.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Dianette, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Dianette as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

- ➔ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:
 - carries on for more than the first few months
 - starts after you've been taking Dianette for a while
 - carries on even after you've stopped taking Dianette.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Dianette

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C
- Do not use Dianette after the expiry date shown on the strip.
- If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do
- Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Dianette and who makes it

Your medicine

Each box of Dianette contains three strips of 21 yellow sugar-coated tablets. Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Dianette also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Pharma AG, Mullerstrasse 170-178, D-13353 Berlin, Germany and is procured from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL Number: 15184/1298

Leaflet revision date: 05/05/16

Dianette is a registered trademark of Bayer Intellectual Property GmbH.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Dianette® Tablets

(cyproterone acetate/ethinylestradiol)

Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Your medicine is called Dianette Tablets, and will be referred to as Dianette throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

- Read all of this leaflet carefully before you start taking this medicine.**
- Keep this leaflet. You may need to read it again.
 - If you have any questions or need more advice, ask your doctor, or pharmacist.
 - This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
 - **If any of the side effects gets severe,** or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Dianette is and what it is used for**
- 2 What you need to know before you take Dianette**

- 2.1 Before you take Dianette**
- When should you contact your doctor
 - Dianette and cancer

- 2.2 Make sure Dianette is OK for you**
- Dianette should not be taken by some women
 - Dianette can make some illnesses worse
 - Taking other medicines
 - Taking Dianette with food and drink
 - Pregnancy and breast-feeding
 - Driving and using machines
 - Dianette contains lactose
 - Dianette and sun-beds or sun-lamps

3 Taking Dianette

- Duration of use
- How to take it
- Starting Dianette
- A missed pill
- A lost pill
- If you are sick or have diarrhoea
- Missed a period – could you be pregnant?
- Taking more than one pill should not cause harm
- When you want to get pregnant

4 Possible side effects

- 4.1 Serious side effects – see a doctor straight away
- 4.2 Less serious side effects
- 4.3 Bleeding between periods should not last long

5 How to store Dianette

6 What is in Dianette and who makes it

1 What Dianette is and what it is used for

Dianette contains an oestrogen and an anti-androgen. Dianette is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Dianette if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics. If you are taking Dianette for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Dianette, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Dianette stops the androgens affecting your skin and reduces the amount of androgens produced.

Ref:1298/050516/2/F

Contraception

Dianette is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Dianette will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Dianette needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Dianette

2.1 Before you take Dianette

It's important that you understand the benefits and risks of taking Dianette before you start taking it, or when deciding whether to carry on taking it. Although Dianette is suitable for most healthy women it isn't suitable for everyone.

- ➔ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Dianette

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on Dianette

- You will need **regular check-ups** with your doctor, usually when you need another prescription of Dianette.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Dianette, because this type of medicine can affect the results of some tests.
- **If you're going to have an operation,** make sure your doctor knows about it. You may need to stop taking Dianette about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Dianette again.
- **If you need to stop taking Dianette,** remember to use another contraceptive (e.g. condoms) if you are relying on Dianette for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in 'Blood clots (Thrombosis)' and in Section 4. Dianette also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Dianette may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Dianette compared with women who do not take Dianette or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Dianette.

- Of 100,000 women who are **not taking Dianette, not on the Pill** and not pregnant, about **5 to 10** will have a blood clot in a year.
- Of 100,000 women who **take Dianette or the Pill,** up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant,** around **60** will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- **if you smoke.**

When using a hormonal contraceptive like Dianette you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Dianette, as the treatment may have to be stopped. Your doctor may tell you to stop using Dianette several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Dianette again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke**.
 - **When using a hormonal contraceptive like Dianette you are strongly advised to stop smoking, especially if you are older than 35 years**;
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Dianette.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Dianette and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Dianette also provide the same protective effects. However, it also seems that taking Dianette slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Dianette. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Dianette or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Dianette, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Dianette users is small. For example:

- Of 10,000 women who have **never taken Dianette or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take Dianette or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Dianette or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Dianette or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
 - ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Dianette has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Dianette has also been linked with some forms of liver cancer in women who have taken it for a long time.
 - ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Dianette.

2.2 Make sure Dianette is OK for you

Dianette should not be taken by some women

- ➔ **Tell your doctor** if you have any medical problems or illnesses.
- Do not take Dianette** Tell your doctor if any of the following conditions applies to you before starting to use Dianette. Your doctor may then advise you to use a different treatment:
 - If you are using another hormonal **contraceptive**
 - If you are **pregnant** or might be pregnant
 - If you are **breast-feeding**
 - If you have or have ever had **breast cancer**
 - If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
 - If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or **‘mini-stroke’** (transient ischaemic attack)
 - If you have (or have ever had) a **heart attack** or **stroke**.
 - If you have a condition that may increase the risk of a **blood clot** in your arteries. This applies to the following conditions:
 - **diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
 - If you have problems with **blood clotting** (e.g. protein C deficiency)
 - If you have (or have ever had) a **migraine, with visual disturbances**
 - If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
 - If you have ever had **liver tumours**
 - If you are **allergic** (*hypersensitive*) to any of the ingredients in Dianette.
- ➔ **If you suffer from any of these**, or get them for the first time while taking Dianette, contact your doctor as soon as possible. Do not take Dianette. If needed, use another form of contraception.

Dianette can make some illnesses worse

- Some of the conditions listed below can be made worse by taking Dianette. Or they may mean it is less suitable for you. You may still be able to take Dianette but you need to take special care and have check-ups more often.
- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
 - If you or your close family have ever had problems with **blood clotting**
 - If you have had **migraines**
 - If you are currently suffering from **depression** or have done so in the past
 - If you are **overweight** (*obese*)
 - If you have the inherited disease called **porphyria**
 - If you have **diabetes**
 - If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
 - If you have **brown patches on your face or body** (chloasma) (see below ‘Dianette and sun-beds or sun-lamps’)
 - If you have any **illness that worsened during pregnancy or previous use of the Pill** or **Dianette** (see section 4)

➔ **Tell your doctor if any apply to you.** Also tell them if you get any of these for the first time while taking Dianette, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Dianette, always tell your doctor, pharmacist or dentist that you’re taking Dianette. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Dianette for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines can have an influence on the blood levels of Dianette and can stop it from working properly- for example

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics** (oral tetracyclines)
- **certain sedatives** (called *barbiturates*)
- **St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Dianette may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Dianette can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Dianette can also interfere with the results of some blood tests, so always tell your doctor that you are taking Dianette if you have a blood test

Taking Dianette with food and drink

There are no special instructions about food and drink while on Dianette.

Pregnancy and breast-feeding

Do not use Dianette if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Dianette.

Driving and using machines

Dianette has no known effect on the ability to drive or use machines.

Dianette contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Dianette.

Dianette and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Dianette. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3 Taking Dianette

Your doctor has chosen Dianette as a treatment for your acne or excessive hair growth on your face and body. However, Dianette also has a contraceptive effect, so it is important to follow the advice below if you are relying on Dianette for contraception.

If you are only using Dianette for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Dianette.

How to take it

Take Dianette every day for 21 days

Dianette comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Dianette as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight Start taking your next strip of Dianette after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time. As long as you take Dianette correctly, you will always start each new strip on the same day of the week.

Starting Dianette

New users or starting Dianette after a break

It is best to take your first Dianette pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Dianette from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Dianette the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Dianette.
- **If you are taking a 28-day Pill:** start taking Dianette the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Dianette.
- **If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Dianette on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Dianette after a miscarriage or abortion

If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Dianette straight away.

This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Dianette should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Dianette and for the first 7 days of pill taking.

Do not take Dianette if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.
- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.
- **Use extra contraception for seven days after missing a pill**, such as condoms.
- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

- **Contact your doctor or do a pregnancy test yourself.**

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Dianette**, follow the instructions in section 3.4 A lost pill, which describes how to take another pill. If you are still sick or have diarrhoea **more than 12 hours after taking Dianette**, see section 3.3, *A missed pill*.

- ➔ **Talk to your doctor if your stomach upset carries on or gets worse.**

He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Dianette and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Dianette until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

Like all medicines, Diane 35 can cause side effects, although not everybody gets them.

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Diane 35.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Diane 35, you should stop Diane 35 as a precaution, if you develop severe depression, and see your doctor straight away

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- swelling of the hands, face, lips, mouth, tongue or throat.**
- A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- dimpling** of the skin
- changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- pelvic pain**
- painful sex.**

Signs of severe liver problems include:

- severe **pain in your stomach**
- yellow skin or eyes** (*jaundice*)
- inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

➔ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Diane 35.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- feeling sick**
- stomach ache**
- putting on weight**
- headaches**
- depressive moods or mood swings**
- sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- being sick and stomach upsets**
- fluid retention**
- migraine**
- loss of interest in sex**
- breast enlargement**
- skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- poor tolerance of contact lenses**
- losing weight**
- increase of interest in sex**
- vaginal or breast discharge**
- venous blood clot**

Other side effects reported

- bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Diane 35. If it continues, becomes heavy or starts again, contact your doctor
- chloasma** (yellow brown patches on the skin). This may happen even if you have been using Diane 35 for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurence or deterioration of the movement disorder **chorea**
- Crohn’s disease** or **ulcerative colitis**
- increase in blood pressure

● **conditions that may worsen during pregnancy or previous use of the Pill:**

- yellowing of the skin** (*jaundice*)
- persistent itching** (*pruritus*)
- kidney or liver problems**
- gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- blister-like rash** (*herpes gestationis*) whilst pregnant
- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- swelling of body parts** (*hereditary angioedema*)
- an inherited disease called **porphyria**
- cancer of the cervix**

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Diane 35. Also tell them if any existing conditions get worse while you are taking Diane 35.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Diane 35, especially during the first few months. Normally, this bleed-ing is nothing to worry about and will stop after a day or two. Keep taking Diane 35 as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

➔ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Diane 35 for a while
- carries on even after you've stopped taking Diane 35.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Diane 35

- Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C
- Do not use Diane 35 after the expiry date shown on the strip.
- If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do
- Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Diane 35 and who makes it

Your medicine

Each box of Diane 35 contains three strips of 21 yellow sugar-coated tablets. Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Diane 35 also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar, Germany and is prescribed from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL Number: 15184/1298

Leaflet revision date: 05/05/16

Diane 35 is a registered trademark of Bayer Intellectual Property GmbH.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Diane 35® Tablets (cyproterone acetate/ethinylestradiol) Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. Your medicine is called Diane 35 Tablets, and will be referred to as Diane 35 throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1 What Diane 35 is and what it is used for

2 What you need to know before you take Diane 35

2.1 Before you take Diane 35

When should you contact your doctor Diane 35 and cancer

2.2 Make sure Diane 35 is OK for you

Diane 35 should not be taken by some women Diane 35 can make some illnesses worse Taking other medicines Taking Diane 35 with food and drink Pregnancy and breast-feeding Driving and using machines Diane 35 contains lactose Diane 35 and sun-beds or sun-lamps

3 Taking Diane 35

Duration of use How to take it Starting Diane 35 A missed pill A lost pill If you are sick or have diarrhoea Missed a period – could you be pregnant? Taking more than one pill should not cause harm When you want to get pregnant

4 Possible side effects

4.1 Serious side effects – see a doctor straight away

4.2 Less serious side effects

4.3 Bleeding between periods should not last long

5 How to store Diane 35

6 What is in Diane 35 and who makes it

1 What Diane 35 is and what it is used for

Diane 35 contains an oestrogen and an anti-androgen. Diane 35 is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Diane 35 if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics. If you are taking Diane 35 for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Diane 35, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Diane 35 stops the androgens affecting your skin and reduces the amount of androgens produced.

Contraception

Diane 35 is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Diane 35 will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Diane 35 needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Diane 35

2.1 Before you take Diane 35

It’s important that you understand the benefits and risks of taking Diane 35 before you start taking it, or when deciding whether to carry on taking it. Although Diane 35 is suitable for most healthy women it isn’t suitable for everyone.

➔ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Diane 35

- Your doctor will ask about you and your family’s medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you’re on Diane 35

- You will need **regular check-ups** with your doctor usually when you need another prescription of Diane 35.
- You should go for **regular cervical smear** tests.
- Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- If you need a blood test** tell your doctor that you are taking Diane 35, because this type of medicine can affect the results of some tests.
- If you’re going to have an operation**, make sure your doctor knows about it. You may need to stop taking Diane 35 about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Diane 35 again.
- If you need to stop taking Diane 35**, remember to use another contraceptive (e.g. condoms) if you are relying on Diane 35 for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in ‘Blood clots (Thrombosis)’ and in Section 4. Diane 35 also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Diane 35 may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Diane 35 compared with women who do not take Diane 35 or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a ‘venous thrombosis’) can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman’s risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Diane 35.

- Of 100,000 women who are **not taking Diane 35, not on the Pill** and not pregnant, about 5 to 10 will have a blood clot in a year.
- Of 100,000 women who **take Diane 35 or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around 60 will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;

- if you smoke.**

When using a hormonal contraceptive like Diane 35 you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Diane 35, as the treatment may have to be stopped. Your doctor may tell you to stop using Diane 35 several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Diane 35 again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- if you smoke**.
 - When using a hormonal contraceptive like Diane 35 you are strongly advised to stop smoking, especially if you are older than 35 years;**
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Diane 35.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Diane 35 and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Diane 35 also provide the same protective effects. However, it also seems that taking Diane 35 slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Diane 35. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Diane 35 or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Diane 35, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Diane 35 users is small. For example:

- Of 10,000 women who have **never taken Diane 35 or the Pill**, about 16 will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Diane 35 or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Diane 35 or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Diane 35 or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

If you do need to take one of these medicines, Diane 35 may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
- ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Diane 35 has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Diane 35 has also been linked with some forms of liver cancer in women who have taken it for a long time.
- ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Diane 35.

2.2 Make sure Diane 35 is OK for you

Diane 35 should not be taken by some women

➔ **Tell your doctor** if you have any medical problems or illnesses.

Do not take Diane 35 Tell your doctor if any of the following conditions applies to you before starting to use Diane 35. Your doctor may then advise you to use a different treatment:

- If you are using another hormonal **contraceptive**
- If you are **pregnant** or might be pregnant
- If you are **breast-feeding**
- If you have or have ever had **breast cancer**
- If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or ‘**mini-stroke**’ (transient ischaemic attack)
- If you have (or have ever had) a **heart attack or stroke**.
- If you have a condition that may increase the risk of a blood clot in your arteries. This applies to the following conditions:
 - diabetes affecting your blood vessels**
 - very high blood pressure
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
 - if you have problems with **blood clotting** (e.g. protein C deficiency)
 - If you have (or have ever had) a **migraine, with visual disturbances**
 - If you have ever had a severe liver disease, and you have been told by your doctor that your liver test results are not yet back to normal
 - If you have ever had **liver tumours**
 - If you are **allergic** (*hypersensitive*) to any of the ingredients in Diane 35.
- ➔ **If you suffer from any of these**, or get them for the first time while taking Diane 35, contact your doctor as soon as possible. Do not take Diane 35. If needed, use another form of contraception.

Diane 35 can make some illnesses worse

Some of the conditions listed below can be made worse by taking Diane 35. Or they may mean it is less suitable for you. You may still be able to take Diane 35 but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (obese)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (*chloasma*) (see below ‘Diane 35 and sun-beds or sun-lamps’)
- If you have any **illness that worsened during pregnancy or previous use of the Pill or Diane 35** (see section 4)
- ➔ **Tell your doctor if any apply to you**. Also tell them if you get any of these for the first time while taking Diane 35, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Diane 35, always tell your doctor, pharmacist or dentist that you’re taking Diane 35. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Diane 35 for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines can have an influence on the blood levels of Diane 35 and can stop it from working properly-for example.

- some medicines used to treat epilepsy**
- some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- griseofulvin** (an anti-fungal medicine)
- certain antibiotics** (oral tetracyclines)
- certain sedatives** (called *barbiturates*)
- St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Diane 35 may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Diane 35 can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Diane 35 can also interfere with the results of some blood tests, so always tell your doctor that you are taking Diane 35 if you have a blood test

Taking Diane 35 with food and drink

There are no special instructions about food and drink while on Diane 35.

Pregnancy and breast-feeding

Do not use Diane 35 if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Diane 35.

Driving and using machines

Diane 35 has no known effect on the ability to drive or use machines.

Diane 35 contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Diane 35.

Diane 35 and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Diane 35. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3	Taking Diane 35
----------	------------------------

Your doctor has chosen Diane 35 as a treatment for your acne or excessive hair growth on your face and body. However, Diane 35 also has a contraceptive effect, so it is important to follow the advice below if you are relying on Diane 35 for contraception.

If you are only using Diane 35 for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Diane 35.

How to take it

Take Diane 35 every day for 21 days

Diane 35 comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.
- Then have seven pill-free days**

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Diane 35 as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.
Start your next strip on day eight Start taking your next strip of Diane 35 after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Diane 35 correctly, you will always start each new strip on the same day of the week.

Starting Diane 35

New users or starting Diane 35 after a break

It is best to take your first Diane 35 pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Diane 35 from another contraceptive Pill

- If you are currently taking a 21-day Pill:** start Diane 35 the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane 35.
- If you are taking a 28-day Pill:** start taking Diane 35 the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane 35.
- If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Diane 35 on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Diane 35 after a miscarriage or abortion

If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Diane 35 straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Diane 35 should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Diane 35 and for the first 7 days of pill taking.

Do not take Diane 35 if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.

- Continue to take a pill every day for the next seven days** at your usual time.

- If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.

- Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.
Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Diane 35**, follow the instructions in section 3.4 A lost pill, which describes how to take another pill. If you are still sick or have diarrhoea more than 12 hours after **taking Diane 35**, see section 3.3, A missed pill.

➔ **Talk to your doctor if your stomach upset carries on or gets worse.**

He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Diane 35 and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Diane 35 until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

Ref:1298/050516/3/B	Page 3
---------------------	--------

4 Possible side effects

Like all medicines, Diane 35 can cause side effects, although not everybody gets them.

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Diane 35.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Diane 35, you should stop Diane 35 as a precaution, if you develop severe depression, and see your doctor straight away

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling** of the **hands, face, lips, mouth, tongue or throat.**
- A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- **severe pain in your stomach**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

➔ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Diane 35.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- **feeling sick**
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**
- **venous blood clot**

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Diane 35. If it continues, becomes heavy or starts again, contact your doctor
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Diane 35 for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurrence or deterioration of the movement disorder **chorea**
- **Crohn’s disease** or **ulcerative colitis**
- increase in blood pressure

- **conditions that may worsen during pregnancy or previous use of the Pill:**

- **yellowing of the skin** (*jaundice*)
- **persistent itching** (*pruritus*)
- **kidney or liver problems**
- **gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- **blister-like rash** (*herpes gestationis*) whilst pregnant
- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- **swelling of body parts** (*hereditary angioedema*)
- an inherited disease called **porphyria**
- **cancer of the cervix**

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Diane 35. Also tell them if any existing conditions get worse while you are taking Diane 35.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Diane 35, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Diane 35 as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

➔ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Diane 35 for a while
- carries on even after you've stopped taking Diane 35.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Diane 35

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C
- Do not use Diane 35 after the expiry date shown on the strip.
- If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do
- Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Diane 35 and who makes it

Your medicine

Each box of Diane 35 contains three strips of 21 yellow sugar-coated tablets. Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Diane 35 also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Pharma AG, Mullerstrasse 170-178, D-13353 Berlin, Germany and is procured from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL Number: 15184/1298

Leaflet revision date: 05/05/16

Diane 35 is a registered trademark of Bayer Intellectual Property GmbH.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Diane 35® Tablets

(cyproterone acetate/ethinylestradiol)

Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. Your medicine is called Diane 35 Tablets, and will be referred to as Diane 35 throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Diane 35 is and what it is used for**
- 2 What you need to know before you take Diane 35**

2.1 Before you take Diane 35

When should you contact your doctor
Diane 35 and cancer

2.2 Make sure Diane 35 is OK for you

Diane 35 should not be taken by some women
Diane 35 can make some illnesses worse
Taking other medicines
Taking Diane 35 with food and drink
Pregnancy and breast-feeding
Driving and using machines
Diane 35 contains lactose
Diane 35 and sun-beds or sun-lamps

3 Taking Diane 35

Duration of use
How to take it
Starting Diane 35
A missed pill
A lost pill
If you are sick or have diarrhoea
Missed a period – could you be pregnant?
Taking more than one pill should not cause harm
When you want to get pregnant

4 Possible side effects

- 4.1 Serious side effects – see a doctor straight away
- 4.2 Less serious side effects
- 4.3 Bleeding between periods should not last long

5 How to store Diane 35

6 What is in Diane 35 and who makes it

1 What Diane 35 is and what it is used for

Diane 35 contains an oestrogen and an anti-androgen. Diane 35 is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Diane 35 if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics. If you are taking Diane 35 for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Diane 35, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Diane 35 stops the androgens affecting your skin and reduces the amount of androgens produced.

Ref:1298/050516/4/F

Contraception

Diane 35 is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Diane 35 will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Diane 35 needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Diane 35

2.1 Before you take Diane 35

It's important that you understand the benefits and risks of taking Diane 35 before you start taking it, or when deciding whether to carry on taking it. Although Diane 35 is suitable for most healthy women it isn't suitable for everyone.

➔ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Diane 35

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on Diane 35

- You will need **regular check-ups** with your doctor usually when you need another prescription of Diane 35.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Diane 35, because this type of medicine can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking Diane 35 about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Diane 35 again.
- **If you need to stop taking Diane 35**, remember to use another contraceptive (e.g. condoms) if you are relying on Diane 35 for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in 'Blood clots (Thrombosis)' and in Section 4. Diane 35 also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Diane 35 may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Diane 35 compared with women who do not take Diane 35 or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Diane 35.

- Of 100,000 women who are **not taking Diane 35, not on the Pill** and not pregnant, about 5 to 10 will have a blood clot in a year.
- Of 100,000 women who **take Diane 35 or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around 60 will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- **if you smoke.**

When using a hormonal contraceptive like Diane 35 you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Diane 35, as the treatment may have to be stopped. Your doctor may tell you to stop using Diane 35 several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Diane 35 again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- if you smoke**.
 - When using a hormonal contraceptive like Diane 35 you are strongly advised to stop smoking, especially if you are older than 35 years**;
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Diane 35.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Diane 35 and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Diane 35 also provide the same protective effects. However, it also seems that taking Diane 35 slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Diane 35. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Diane 35 or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Diane 35, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Diane 35 users is small. For example:

- Of 10,000 women who have **never taken Diane 35 or the Pill**, about 16 will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Diane 35 or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Diane 35 or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Diane 35 or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
 - ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Diane 35 has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Diane 35 has also been linked with some forms of liver cancer in women who have taken it for a long time.
 - ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Diane 35.

2.2 Make sure Diane 35 is OK for you

Diane 35 should not be taken by some women

- ➔ **Tell your doctor** if you have any medical problems or illnesses. **Do not take Diane 35** Tell your doctor if any of the following conditions applies to you before starting to use Diane 35. Your doctor may then advise you to use a different treatment:
 - If you are using another hormonal **contraceptive**
 - If you are **pregnant** or might be pregnant
 - If you are **breast-feeding**
 - If you have or have ever had **breast cancer**
 - If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
 - If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or **'mini-stroke'** (transient ischaemic attack)
 - If you have (or have ever had) a **heart attack** or **stroke**.
 - If you have a condition that may increase the risk of a blood clot in your arteries. This applies to the following conditions:
 - diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
 - If you have problems with **blood clotting** (e.g. protein C deficiency)
 - If you have (or have ever had) a **migraine, with visual disturbances**
 - If you have ever had a severe liver disease, and you have been told by your doctor that your liver test results are not yet back to normal
 - If you have ever had **liver tumours**
 - If you are **allergic** (*hypersensitive*) to any of the ingredients in Diane 35.
- ➔ **If you suffer from any of these**, or get them for the first time while taking Diane 35, contact your doctor as soon as possible. Do not take Diane 35. If needed, use another form of contraception.

Diane 35 can make some illnesses worse

Some of the conditions listed below can be made worse by taking Diane 35. Or they may mean it is less suitable for you. You may still be able to take Diane 35 but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (obese)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (*chloasma*) (see below 'Diane 35 and sun-beds or sun-lamps')
- If you have any **illness that worsened during pregnancy or previous use of the Pill or Diane 35** (see section 4)

➔ **Tell your doctor if any apply to you.** Also tell them if you get any of these for the first time while taking Diane 35, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Diane 35, always tell your doctor, pharmacist or dentist that you’re taking Diane 35.

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives. If you are taking Diane 35 for skin treatment, you must not take any other hormonal contraceptive at the same time. Some medicines can stop Diane 35 from working properly – for example:

- some medicines used to treat epilepsy**
- some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- griseofulvin** (an anti-fungal medicine)
- certain antibiotics** (oral tetracyclines)
- certain sedatives** (called *barbiturates*)
- St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Diane 35 may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long. Some medicines can have an influence on the blood levels of Diane 35 and can stop it from working properly - for example

Diane 35 can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Diane 35 can also interfere with the results of some blood tests, so always tell your doctor that you are taking Diane 35 if you have a blood test

Taking Diane 35 with food and drink

There are no special instructions about food and drink while on Diane 35.

Pregnancy and breast-feeding

Do not use Diane 35 if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Diane 35.

Driving and using machines

Diane 35 has no known effect on the ability to drive or use machines.

Diane 35 contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Diane 35.

Diane 35 and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Diane 35. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3 Taking Diane 35

Your doctor has chosen Diane 35 as a treatment for your acne or excessive hair growth on your face and body. However, Diane 35 also has a contraceptive effect, so it is important to follow the advice below if you are relying on Diane 35 for contraception.

If you are only using Diane 35 for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Diane 35.

How to take it

Take Diane 35 every day for 21 days

Diane 35 comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Diane 35 as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight Start taking your next strip of Diane 35 after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Diane 35 correctly, you will always start each new strip on the same day of the week.

Starting Diane 35

New users or starting Diane 35 after a break

It is best to take your first Diane 35 pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Diane 35 from another contraceptive Pill

- If you are currently taking a 21-day Pill:** start Diane 35 the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane 35.
- If you are taking a 28-day Pill:** start taking Diane 35 the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Diane 35.
- If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Diane 35 on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Diane 35 after a miscarriage or abortion

If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Diane 35 straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Diane 35 should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Diane 35 and for the first 7 days of pill taking.

Do not take Diane 35 if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- Continue to take a pill every day for the next seven days** at your usual time.

- If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.

- Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Diane 35**, follow the instructions in section 3.4 A lost pill, which describes how to take another pill. If you are still sick or have diarrhoea more than 12 hours after **taking Diane 35**, see section 3.3. A missed pill.

➔ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Diane 35 and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Diane 35 until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

Like all medicines, Co-cyprindiol can cause side effects, although not everybody gets them.

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Co-cyprindiol.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Co-cyprindiol, you should stop Co-cyprindiol as a precaution, if you develop severe depression, and see your doctor straight away

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- swelling of the hands, face, lips, mouth, tongue or throat.**
- A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- dimpling** of the skin
- changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- pelvic pain**
- painful sex.**

Signs of severe liver problems include:

- severe pain in your stomach
- yellow skin or eyes** (*jaundice*)
- inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

➔ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Co-cyprindiol.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- feeling sick**
- stomach ache**
- putting on weight**
- headaches**
- depressive moods or mood swings**
- sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- being sick and stomach upsets**
- fluid retention**
- migraine**
- loss of interest in sex**
- breast enlargement**
- skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- poor tolerance of contact lenses**
- losing weight**
- increase of interest in sex**
- vaginal or breast discharge**
- venous blood clot**

Other side effects reported

- bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Co-cyprindiol. If it continues, becomes heavy or starts again, contact your doctor
- chloasma** (yellow brown patches on the skin). This may happen even if you have been using Co-cyprindiol for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurence or deterioration of the movement disorder **chorea**
- Crohn's disease or ulcerative colitis**
- increase in blood pressure

● **conditions that may worsen during pregnancy or previous use of the Pill:**

- yellowing of the skin** (*jaundice*)
- persistent itching** (*pruritus*)
- kidney or liver problems**
- gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- blister-like rash** (*herpes gestationis*) whilst pregnant
- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- swelling of body parts** (*hereditary angioedema*)
- an inherited disease called **porphyria**
- cancer of the cervix**

➔ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Co-cyprindiol. Also tell them if any existing conditions get worse while you are taking Co-cyprindiol.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Co-cyprindiol, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Co-cyprindiol as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

➔ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Co-cyprindiol for a while
- carries on even after you've stopped taking Co-cyprindiol.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

<p>5</p> <p>How to store Co-cyprindiol</p> <ul style="list-style-type: none">Keep this medicine out of the sight and reach of children. Do not store above 25°C Do not use Co-cyprindiol after the expiry date shown on the strip. If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Co-cyprindiol and who makes it

Your medicine

Each box of Co-cyprindiol contains three strips of 21 yellow sugar-coated tablets.

Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Co-cyprindiol also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar, Germany and is procured from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM	PL Number: 15184/1298
------------	-----------------------

Leaflet revision date: 05/05/16

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Co-cyprindiol 2000/35 Tablets

(cyproterone acetate/ethinylestradiol)

Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Your medicine is called Co-cyprindiol 2000/35 Tablets, and will be referred to as Co-cyprindiol throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1 What Co-cyprindiol is and what it is used for

2 What you need to know before you take Co-cyprindiol

2.1 Before you take Co-cyprindiol

When should you contact your doctor
Co-cyprindiol and cancer

2.2 Make sure Co-cyprindiol is OK for you

Co-cyprindiol should not be taken by some women

Co-cyprindiol can make some illnesses worse

Taking other medicines

Taking Co-cyprindiol with food and drink

Pregnancy and breast-feeding

Driving and using machines

Co-cyprindiol contains lactose

Co-cyprindiol and sun-beds or sun-lamps

3 Taking Co-cyprindiol

Duration of use

How to take it

Starting Co-cyprindiol

A missed pill

A lost pill

If you are sick or have diarrhoea

Missed a period – could you be pregnant?

Taking more than one pill should not cause harm

When you want to get pregnant

4 Possible side effects

4.1 Serious side effects – see a doctor straight away

4.2 Less serious side effects

4.3 Bleeding between periods should not last long

5 How to store Co-cyprindiol

6 What is in Co-cyprindiol and who makes it

1 What Co-cyprindiol is and what it is used for

Co-cyprindiol contains an oestrogen and an anti-androgen. Co-cyprindiol is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate. You should only take Co-cyprindiol if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

If you are taking Co-cyprindiol for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Co-cyprindiol, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Co-cyprindiol stops the androgens affecting your skin and reduces the amount of androgens produced.

Ref:1298/050516/5/F

<p>2</p> <p>What you need to know before you take Co-cyprindiol</p> <p>2.1 Before you take Co-cyprindiol</p> <p>It's important that you understand the benefits and risks of taking Co-cyprindiol before you start taking it, or when deciding whether to carry on taking it. Although Co-cyprindiol is suitable for most healthy women it isn't suitable for everyone.</p> <p>➔ Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.</p> <p>Before you start taking Co-cyprindiol</p> <ul style="list-style-type: none">Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

Contraception
Co-cyprindiol is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills. Co-cyprindiol will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

<p>2</p> <p>What you need to know before you take Co-cyprindiol</p> <p>2.1 Before you take Co-cyprindiol</p> <p>It's important that you understand the benefits and risks of taking Co-cyprindiol before you start taking it, or when deciding whether to carry on taking it. Although Co-cyprindiol is suitable for most healthy women it isn't suitable for everyone.</p> <p>➔ Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.</p> <p>Before you start taking Co-cyprindiol</p> <ul style="list-style-type: none">Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on Co-cyprindiol

- You will need **regular check-ups** with your doctor usually when you need another prescription of Co-cyprindiol.
- You should go for **regular cervical smear** tests.
- Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.

- If you need a blood test** tell your doctor that you are taking Co-cyprindiol, because this type of medicine can affect the results of some tests.
- If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking Co-cyprindiol about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Co-cyprindiol again.
- If you need to stop taking Co-cyprindiol**, remember to use another contraceptive (e.g. condoms) if you are relying on Co-cyprindiol for contraception.

When should you contact your doctor
Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in 'Blood clots (Thrombosis)' and in Section 4.
Co-cyprindiol also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.
Blood clots (thrombosis)
Taking Co-cyprindiol may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol compared with women who do not take Co-cyprindiol or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.
Blood clots in a vein
A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ. Using a combined pill increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.
Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol.

- Of 100,000 women who are **not taking Co-cyprindiol, not on the Pill** and not pregnant, about 5 to 10 will have a blood clot in a year.
- Of 100,000 women who **take Co-cyprindiol or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around 60 will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- if you smoke.**

When using a hormonal contraceptive like Co-cyprindiol you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Co-cyprindiol, as the treatment may have to be stopped. Your doctor may tell you to stop using Co-cyprindiol several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Co-cyprindiol again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke**.
- **When using a hormonal contraceptive like Co-cyprindiol you are strongly advised to stop smoking, especially if you are older than 35 years;**
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
 - severe pain in the chest which may reach the left arm;
 - breathlessness;
 - any unusual, severe, or long-lasting headache or worsening of migraine;
 - partial or complete loss of vision, or double vision;
 - slurring or speech disability;
 - sudden changes to your hearing, sense of smell, or taste;
 - dizziness or fainting;
 - weakness or numbness in any part of your body;
 - severe pain in your abdomen;
 - severe pain or swelling in either of your legs.
- Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Co-cyprindiol.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Co-cyprindiol and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Co-cyprindiol also provide the same protective effects. However, it also seems that taking Co-cyprindiol slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Co-cyprindiol. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Co-cyprindiol or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Co-cyprindiol, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Co-cyprindiol users is small. For example:

- Of 10,000 women who have **never taken Co-cyprindiol or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Co-cyprindiol or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Co-cyprindiol or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Co-cyprindiol or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
- ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Co-cyprindiol has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Co-cyprindiol has also been linked with some forms of liver cancer in women who have taken it for a long time.
- ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Co-cyprindiol.

2.2 Make sure Co-cyprindiol is OK for you

Co-cyprindiol should not be taken by some women

➔ **Tell your doctor** if you have any medical problems or illnesses. **Do not take Co-cyprindiol** Tell your doctor if any of the following conditions applies to you before starting to use Co-cyprindiol. Your doctor may then advise you to use a different treatment:

- If you are using another hormonal **contraceptive**
- If you are **pregnant** or might be pregnant
- If you are **breast-feeding**
- If you have or have ever had **breast cancer**
- If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or **‘mini-stroke’** (transient ischaemic attack)
- If you have (or have ever had) a **heart attack** or **stroke**.
- If you have a condition that may increase the risk of a blood clot in your arteries. This applies to the following conditions:
 - **diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
 - If you have problems with **blood clotting** (e.g. protein C deficiency)
 - If you have (or have ever had) a **migraine, with visual disturbances**
 - If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
 - If you have ever had **liver tumours**
 - If you are **allergic** (*hypersensitive*) to any of the ingredients in Co-cyprindiol.

➔ **If you suffer from any of these**, or get them for the first time while taking Co-cyprindiol, **contact your doctor** as soon as possible. Do not take Co-cyprindiol. If needed, use another form of contraception.

Co-cyprindiol can make some illnesses worse

Some of the conditions listed below can be made worse by taking Co-cyprindiol. Or they may mean it is less suitable for you. You may still be able to take Co-cyprindiol but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (obese)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (chloasma) (see below ‘Co-cyprindiol and sun-beds or sun-lamps’)
- If you have any **illness that worsened during pregnancy or previous use of the Pill or Co-cyprindiol** (see section 4)

➔ **Tell your doctor if any apply to you**. Also tell them if you get any of these for the first time while taking Co-cyprindiol, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Co-cyprindiol, always tell your doctor, pharmacist or dentist that you’re taking Co-cyprindiol. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Co-cyprindiol for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines can stop Co-cyprindiol from working properly – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics** (oral tetracyclines)
- **certain sedatives** (called barbiturates)
- **St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Co-cyprindiol may not be suitable for you or you may need to use extra contraception for a while.

Some medicines can have an influence on the blood levels of Co-cyprindiol and can stop it from working properly-for example

Your doctor, pharmacist or dentist can tell you if this is necessary and for how long

Co-cyprindiol can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Co-cyprindiol can also interfere with the results of some blood tests, so always tell your doctor that you are taking Co-cyprindiol if you have a blood test

Taking Co-cyprindiol with food and drink

There are no special instructions about food and drink while on Co-cyprindiol.

Pregnancy and breast-feeding

Do not use Co-cyprindiol if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Co-cyprindiol.

Driving and using machines

Co-cyprindiol has no known effect on the ability to drive or use machines.

Co-cyprindiol contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Co-cyprindiol.

Co-cyprindiol and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Co-cyprindiol. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3 Taking Co-cyprindiol

Your doctor has chosen Co-cyprindiol as a treatment for your acne or excessive hair growth on your face and body. However, Co-cyprindiol also has a contraceptive effect, so it is important to follow the advice below if you are relying on Co-cyprindiol for contraception.

If you are only using Co-cyprindiol for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Co-cyprindiol.

How to take it

Take Co-cyprindiol every day for 21 days

Co-cyprindiol comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Co-cyprindiol as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight Start taking your next strip of Co-cyprindiol after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Co-cyprindiol correctly, you will always start each new strip on the same day of the week.

Starting Co-cyprindiol

New users or starting Co-cyprindiol after a break

It is best to take your first Co-cyprindiol pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Co-cyprindiol from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Co-cyprindiol the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Co-cyprindiol.

- **If you are taking a 28-day Pill:** start taking Co-cyprindiol the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Co-cyprindiol.

- **If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Co-cyprindiol on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Co-cyprindiol after a miscarriage or abortion

If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Co-cyprindiol straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Co-cyprindiol should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Co-cyprindiol and for the first 7 days of pill taking.

Do not take Co-cyprindiol if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.

- **Continue to take a pill every day for the next seven days** at your usual time.

- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.

- **Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before. **Or** if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. If you are better **within 12 hours of taking Co-cyprindiol**, follow the instructions in section 3.4 *A lost pill*, which describes how to take another pill. If you are still sick or have diarrhoea more than 12 hours after **taking Co-cyprindiol**, see section 3.3, A missed pill.

➔ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Co-cyprindiol and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Co-cyprindiol until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

Like all medicines, Co-cyprindiol can cause side effects, although not everybody gets them.

→ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Co-cyprindiol.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Co-cyprindiol, you should stop Co-cyprindiol as a precaution, if you develop severe depression, and see your doctor straight away

Signs of a blood clot:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue or throat.**

A swollen tongue/throat may lead to **difficulty swallowing and breathing**

- a red bumpy rash (*hives*) and itching

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood

- unusual **vaginal bleeding**

- **pelvic pain**

- **painful sex.**

Signs of severe liver problems include:

- severe pain in your stomach
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching**.

If you think you may have any of these, see a doctor straight away.

→ You may need to stop taking Co-cyprindiol.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- feeling sick
- stomach ache
- putting on weight
- headaches
- **depressive moods or mood swings**
- sore or painful breasts

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- being sick and stomach upsets
- fluid retention
- migraine
- loss of interest in sex
- breast enlargement
- skin rash, which may be itchy

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- poor tolerance of contact lenses
- losing weight
- increase of interest in sex
- vaginal or breast discharge
- venous blood clot

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Co-cyprindiol. If it continues, becomes heavy or starts again, contact your doctor
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Co-cyprindiol for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurrence or deterioration of the movement disorder **chorea**
- **Crohn's disease or ulcerative colitis**
- increase in blood pressure

Page 4

• **conditions that may worsen during pregnancy or previous use of the Pill:**

- **yellowing of the skin** (*jaundice*)
- **persistent itching** (*pruritus*)
- **kidney or liver problems**
- **gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- **blister-like rash** (*herpes gestationis*) whilst pregnant
- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- **swelling of body parts** (*hereditary angioedema*)
- an inherited disease called **porphyria**
- **cancer of the cervix**

→ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Co-cyprindiol. Also tell them if any existing conditions get worse while you are taking Co-cyprindiol.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Co-cyprindiol, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Co-cyprindiol as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Co-cyprindiol for a while
- carries on even after you've stopped taking Co-cyprindiol.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Co-cyprindiol

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C
- Do not use Co-cyprindiol after the expiry date shown on the strip.
- If the tablets discoloured or show any signs of deterioration, ask your pharmacist who will advise you what to do
- Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Co-cyprindiol and who makes it

Your medicine

Each box of Co-cyprindiol contains three strips of 21 yellow sugar-coated tablets.

Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

What is in your medicine

Co-cyprindiol also contains the inactive ingredients: lactose monohydrate, maize starch, povidone 25000, povidone 700000, talc, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, titanium dioxide (E171), glycerol 85%, montan glycol wax, yellow ferric oxide (E172)

Manufacturer and Licence Holder

Manufactured by Bayer Pharma AG, Mullerstrasse 170-178, D-13353 Berlin, Germany and is procured from within the EU. Repackaged by Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL Number: 15184/1298

Leaflet revision date: 05/05/16

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 for help.

Co-cyprindiol 2000/35 Tablets

(cyproterone acetate/ethinylestradiol)

Patient Information Leaflet

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. Your medicine is called Co-cyprindiol 2000/35 Tablets, and will be referred to as Co-cyprindiol throughout this leaflet.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1 What Co-cyprindiol is and what it is used for

2 What you need to know before you take Co-cyprindiol

2.1 Before you take Co-cyprindiol

When should you contact your doctor
Co-cyprindiol and cancer

2.2 Make sure Co-cyprindiol is OK for you

Co-cyprindiol should not be taken by some women

Co-cyprindiol can make some illnesses worse

Taking other medicines

Taking Co-cyprindiol with food and drink

Pregnancy and breast-feeding

Driving and using machines

Co-cyprindiol contains lactose

Co-cyprindiol and sun-beds or sun-lamps

3 Taking Co-cyprindiol

Duration of use

How to take it

Starting Co-cyprindiol

A missed pill

A lost pill

If you are sick or have diarrhoea

Missed a period – could you be pregnant?

Taking more than one pill should not cause harm

When you want to get pregnant

4 Possible side effects

4.1 Serious side effects – see a doctor straight away

4.2 Less serious side effects

4.3 Bleeding between periods should not last long

5 How to store Co-cyprindiol

6 What is in Co-cyprindiol and who makes it

1 What Co-cyprindiol is and what it is used for

Co-cyprindiol contains an oestrogen and an anti-androgen. Co-cyprindiol is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Co-cyprindiol if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

If you are taking Co-cyprindiol for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Co-cyprindiol, you will need to go back to your original/preferred method of contraception

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Co-cyprindiol stops the androgens affecting your skin and reduces the amount of androgens produced.

Ref:1298/050516/E/F

Contraception

Co-cyprindiol is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

Co-cyprindiol will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Co-cyprindiol needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Co-cyprindiol

2.1 Before you take Co-cyprindiol

It's important that you understand the benefits and risks of taking

Co-cyprindiol before you start taking it, or when deciding whether to carry on taking it. Although Co-cyprindiol is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Co-cyprindiol

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on Co-cyprindiol

- You will need **regular check-ups** with your doctor usually when you need another prescription of Co-cyprindiol.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Co-cyprindiol, because this type of medicine can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking Co-cyprindiol about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Co-cyprindiol again.
- **If you need to stop taking Co-cyprindiol**, remember to use another contraceptive (e.g. condoms) if you are relying on Co-cyprindiol for contraception.

When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described below in 'Blood clots (Thrombosis)' and in Section 4. Co-cyprindiol also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

Blood clots (thrombosis)

Taking Co-cyprindiol may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol compared with women who do not take Co-cyprindiol or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

Blood clots in a vein

A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman's risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol.

- Of 100,000 women who are **not taking Co-cyprindiol, not on the Pill** and not pregnant, about 5 to 10 will have a blood clot in a year.
- Of 100,000 women who **take Co-cyprindiol or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around 60 will have a blood clot in a year

The risk of blood clots in a vein in users of a combined pill increases further:

- with increasing age;
- **if you smoke.**

When using a hormonal contraceptive like Co-cyprindiol you are strongly advised to stop smoking, especially if you are older than 35 years;

- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;

Page 1

- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast;
- if you have **polycystic ovary syndrome**;
- if you have **recently had a baby**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**, **Crohn’s disease** or **ulcerative colitis**;
- if you have **sickle cell disease**.

If this applies to you, it is important to tell your doctor that you are using Co-cyprindiol, as the treatment may have to be stopped. Your doctor may tell you to stop using Co-cyprindiol several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Co-cyprindiol again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- with increasing age;
- **if you smoke**. **When using a hormonal contraceptive like Co-cyprindiol you are strongly advised to stop smoking, especially if you are older than 35 years**;
- if you are overweight;
- if you have high blood pressure;
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have **polycystic ovary syndrome**;
- if you have **diabetes**;
- if you have certain rare medical conditions such as **systemic lupus erythematosus**;
- if you have **sickle cell disease**.

Symptoms of blood clots

Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot, such as:

- an unusual sudden cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Co-cyprindiol.

See a doctor straight away if you also develop severe depression, a severe allergic reaction, worsening of hereditary angioedema, signs of breast cancer or cervical cancer or signs of severe liver problems (symptoms and signs are described in section 4).

Co-cyprindiol and cancer

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Co-cyprindiol also provide the same protective effects. However, it also seems that taking Co-cyprindiol slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Co-cyprindiol. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Co-cyprindiol or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you’re on Co-cyprindiol, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Co-cyprindiol users is small. For example:

- Of 10,000 women who have **never taken Co-cyprindiol or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women **who take Co-cyprindiol or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Co-cyprindiol or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Co-cyprindiol or the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight
- ➔ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.
- Taking Co-cyprindiol has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Co-cyprindiol has also been linked with some forms of liver cancer in women who have taken it for a long time.
- ➔ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (*jaundice*). You may need to stop taking Co-cyprindiol.

2.2 Make sure Co-cyprindiol is OK for you

Co-cyprindiol should not be taken by some women

- ➔ **Tell your doctor** if you have any medical problems or illnesses.
- Do not take Co-cyprindiol** Tell your doctor if any of the following conditions applies to you before starting to use Co-cyprindiol. Your doctor may then advise you to use a different treatment:
 - If you are using another hormonal **contraceptive**
 - If you are **pregnant** or might be pregnant
 - If you are **breast-feeding**
 - If you have or have ever had **breast cancer**
 - If you have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
 - If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or **‘mini-stroke’** (transient ischaemic attack)
 - If you have (or have ever had) a **heart attack** or **stroke**.
 - If you have a condition that may increase the risk of a blood clot in your arteries. This applies to the following conditions:
 - **diabetes affecting your blood vessels**
 - very high **blood pressure**
 - a very high level of **fat in your blood** (cholesterol or triglycerides)
 - If you have problems with **blood clotting** (e.g. protein C deficiency)
 - If you have (or have ever had) a **migraine, with visual disturbances**
 - If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
 - If you have ever had **liver tumours**
 - If you are **allergic** (*hypersensitive*) to any of the ingredients in Co-cyprindiol.

- ➔ **If you suffer from any of these**, or get them for the first time while taking Co-cyprindiol, contact your doctor as soon as possible. Do not take Co-cyprindiol. If needed, use another form of contraception.

Co-cyprindiol can make some illnesses worse

Some of the conditions listed below can be made worse by taking Co-cyprindiol. Or they may mean it is less suitable for you. You may still be able to take Co-cyprindiol but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (obese)
- If you have the inherited disease called **porphyria**
- If you have **diabetes**
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (chloasma) (see below ‘Co-cyprindiol and sun-beds or sun-lamps’)
- If you have any **illness that worsened during pregnancy or previous use of the Pill or Co-cyprindiol** (see section 4)

- ➔ **Tell your doctor if any apply to you**. Also tell them if you get any of these for the first time while taking Co-cyprindiol, or if any get worse or come back, because you may need to stop taking it.

Taking other medicines

If you ever need to take another medicine at the same time as taking Co-cyprindiol, always tell your doctor, pharmacist or dentist that you’re taking Co-cyprindiol. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

If you are taking Co-cyprindiol for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines can stop Co-cyprindiol from working properly – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics** (oral tetracyclines)
- **certain sedatives** (called barbiturates)
- **St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Co-cyprindiol may not be suitable for you or you may need to use extra contraception for a while. Some medicines can have an influence on the blood levels of Co-cyprindiol and canstop it from working properly-for example

Your doctor, pharmacist or dentist can tell you if this is necessary and for how long

Co-cyprindiol can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine. In addition, Co-cyprindiol can also interfere with the results of some blood tests, so always tell your doctor that you are taking Co-cyprindiol if you have a blood test

Taking Co-cyprindiol with food and drink

There are no special instructions about food and drink while on Co-cyprindiol.

Pregnancy and breast-feeding

Do not use Co-cyprindiol if you are pregnant or are breast-feeding. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Co-cyprindiol.

Driving and using machines

Co-cyprindiol has no known effect on the ability to drive or use machines.

Co-cyprindiol contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Co-cyprindiol.

Co-cyprindiol and sun-beds or sun-lamps

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Co-cyprindiol. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3 Taking Co-cyprindiol

Your doctor has chosen Co-cyprindiol as a treatment for your acne or excessive hair growth on your face and body. However, Co-cyprindiol also has a contraceptive effect, so it is important to follow the advice below if you are relying on Co-cyprindiol for contraception. If you are only using Co-cyprindiol for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

Duration of use

Your doctor will tell you how long you need to keep taking Co-cyprindiol.

How to take it

Take Co-cyprindiol every day for 21 days

Co-cyprindiol comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Co-cyprindiol as described here. You don’t need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight Start taking your next strip of Co-cyprindiol after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Co-cyprindiol correctly, you will always start each new strip on the same day of the week.

Starting Co-cyprindiol

New users or starting Co-cyprindiol after a break

It is best to take your first Co-cyprindiol pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Co-cyprindiol from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Co-cyprindiol the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Co-cyprindiol.
- **If you are taking a 28-day Pill:** start taking Co-cyprindiol the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Co-cyprindiol.
- **If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Co-cyprindiol on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Co-cyprindiol after a miscarriage or abortion

If you have had a miscarriage or an abortion during the **first three months** of pregnancy, your doctor may tell you to start taking Co-cyprindiol straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Co-cyprindiol should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Co-cyprindiol and for the first 7 days of pill taking.

Do not take Co-cyprindiol if you are breast-feeding

A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don’t worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.

- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won’t have a bleed until after you finish the second strip of pills, but don’t worry. If you finish the second strip of pills and don’t have a bleed, do a pregnancy test before starting another strip.

- **Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant.

Contact your doctor or do a pregnancy test yourself.

If you start a new strip of pills late, or make your ‘week off’ longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before. **Or** if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

➔ **If you are sick or have diarrhoea**

If you are sick (vomit) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. If you are better **within 12 hours of taking Co-cyprindiol**, follow the instructions in section 3.4 *A lost pill*, which describes how to take another pill. If you are still sick or have diarrhoea more than 12 hours after **taking Co-cyprindiol**, see section 3.3, A missed pill.

➔ **Talk to your doctor if your stomach upset carries on or gets worse**. He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Co-cyprindiol and see your doctor.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it’s best to use another method of contraception after stopping Co-cyprindiol until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.