

FLUTIFORM® Inhaler

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FLUTIFORM Inhaler?

FLUTIFORM Inhaler contains the active ingredients fluticasone propionate and formoterol fumarate dihydrate. FLUTIFORM Inhaler is used to help with asthma in people who need regular treatment.

For more information, see Section [1. Why am I using FLUTIFORM Inhaler?](#) in the full CMI.

2. What should I know before I use FLUTIFORM Inhaler?

Do not use if you have ever had an allergic reaction to FLUTIFORM Inhaler or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use FLUTIFORM Inhaler?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLUTIFORM Inhaler and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FLUTIFORM Inhaler?

- The usual dose is two inhalations twice a day: two in the morning and two in the evening.
- Adolescents should not use the highest strength inhaler (FLUTIFORM Inhaler 250 micrograms/10 micrograms).

More instructions can be found in Section [4. How do I use FLUTIFORM Inhaler?](#) in the full CMI.

5. What should I know while using FLUTIFORM Inhaler?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using FLUTIFORM Inhaler.• If you have an Asthma Action Plan, follow it closely at all times.• Tell your doctor if you are going to have an operation, have had an accident or have a severe infection.
Things you should not do	<ul style="list-style-type: none">• Do not take any other medicines for your breathing problems without checking with your doctor.• Do not stop using FLUTIFORM Inhaler or change the dosage without checking with your doctor.• Do not use FLUTIFORM to treat an acute asthma attack.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how FLUTIFORM Inhaler affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not consume alcohol while taking this medicine. Alcohol and FLUTIFORM Inhaler may interfere with each other.
Looking after your medicine	<ul style="list-style-type: none">• Keep your inhaler in a cool, dry place, where the temperature stays below 25 degrees C.• Do not use the inhaler if it has been removed from the foil pouch for over 3 months, or if the dose counter reads "0" (whichever comes first).

For more information, see Section [5. What should I know while using FLUTIFORM Inhaler?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headaches, shaking or tremors, changes in taste, hoarse voice, dry mouth, irritated throat, raised patches in the mouth, sore mouth, throat or tongue, nausea or vomiting, muscle spasms or pain, swelling of legs and ankles, increase in the amount of sugar in your blood, blurred vision or other visual disturbances.

More serious side effects include irregular heart beat or palpitations, chest pain, bruising, nervousness or restlessness, mood changes, worsening of your asthma (shortness of breath, coughing) or serious allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FLUTIFORM® Inhaler

Active ingredient(s): *fluticasone propionate/formoterol fumarate dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUTIFORM Inhaler. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FLUTIFORM Inhaler.**

Where to find information in this leaflet:

- [1. Why am I using FLUTIFORM Inhaler?](#)
- [2. What should I know before I use FLUTIFORM Inhaler?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FLUTIFORM Inhaler?](#)
- [5. What should I know while using FLUTIFORM Inhaler?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FLUTIFORM Inhaler?

FLUTIFORM Inhaler contains two active ingredients called fluticasone propionate and formoterol fumarate dihydrate.

Fluticasone propionate belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are sometimes misused by athletes. Corticosteroids help to reduce swelling and inflammation in the lungs.

Formoterol fumarate dihydrate belongs to a group of medicines known as long-acting beta-2-agonists. Beta-2-agonists help the airways in your lungs to stay open, making it easier for you to breathe.

When used together regularly, fluticasone propionate and formoterol fumarate dihydrate help to control your asthma symptoms and prevent asthma attacks.

Asthma is a disease where the lining of the lungs become inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke, air-borne pollution or other irritants. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough.

FLUTIFORM Inhaler is known as a 'preventer'. It does not work if you are already having an asthma attack, i.e. you are already wheezing and breathless. You will need to use a fast acting 'reliever' medicine if this happens.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

FLUTIFORM Inhaler is not addictive.

This medicine is only available with a doctor's prescription.

2. What should I know before I use FLUTIFORM Inhaler?

Warnings

Do not use FLUTIFORM Inhaler if:

- you are allergic to fluticasone propionate, formoterol fumarate dihydrate or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include wheezing, swelling of the lips/mouth or other parts of the body, difficulty in breathing, lumpy rash ("hives") or fainting.

Do not give FLUTIFORM Inhaler to a child under 12 years, unless directed to by the child's doctor.

FLUTIFORM Inhaler is not recommended for use in children under 12 years. The safety and efficacy of FLUTIFORM Inhaler have not been assessed in children under 12 years of age.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - heart problems or disease, an irregular heartbeat or if you have been told that your heart trace is abnormal
 - an abnormal bulging of a blood vessel wall (aneurysm)
 - liver problems
 - diabetes
 - high blood pressure
 - glaucoma
 - an overactive thyroid gland
 - adrenal glands not working properly
 - tumour of the adrenal gland
 - low blood levels of potassium.
- currently have an infection.
If you use FLUTIFORM Inhaler while you have an infection, the medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.
- have or have had tuberculosis (TB).
- are not sure whether you should be using FLUTIFORM Inhaler.
- are going to have an operation, or are feeling stressed.
You may need additional steroid medicine during these times.

If you have not told your doctor or pharmacist about any of the above, tell them before you use FLUTIFORM Inhaler.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [Section 6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using FLUTIFORM Inhaler during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using FLUTIFORM Inhaler during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and FLUTIFORM Inhaler may interfere with each other. These include:

- medicines to treat depression or mood/mental disorders (such as monoamine oxidase inhibitors, tricyclic antidepressants, phenothiazines), or you have taken any of these types of medicines in the last two weeks
- medicines known as beta-blockers, which may be used to treat high blood pressure or glaucoma including those that are eye drops
- medicines used to treat high blood pressure or fluid build-up
- medicines used to treat heart failure (such as digoxin)
- medicines used to treat abnormal heart rhythms (such as quinidine, disopyramide, procainamide)
- medicines used to treat fungal infections (such as ketoconazole, itraconazole)
- medicines used to treat viral infections, including HIV (such as ritonavir, atazanavir, indinavir, nelfinavir, saquinavir, cobicistat)
- medicines used to treat bacterial infections (antibiotics, such as clarithromycin, telithromycin, furazolidone)
- medicines used to treat allergies, hayfever, coughs, colds and runny nose
- other medicines containing steroids
- certain other medicines used to treat asthma or breathing conditions (such as theophylline or aminophylline)
- medicines used for weight reduction purposes
- medicine to treat Hodgkin's disease (procarbazine)
- medicine to treat Parkinson's disease (levodopa)
- medicine used to treat an underactive thyroid gland (levothyroxine)
- medicine to induce labour (oxytocin)
- alcohol.

These medicines may be affected by or may affect FLUTIFORM Inhaler. If you are taking these medicines, talk to your doctor or pharmacist who will advise you on what to do. You may need to use different amounts of your medicines, or take different medicines.

FLUTIFORM Inhaler contains a very small amount of sodium cromoglycate, however patients who are currently using cromoglycate (to treat conditions such as asthma, allergic rhinitis and allergic conjunctivitis) should continue their normal medication.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using FLUTIFORM Inhaler.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FLUTIFORM Inhaler.

4. How do I use FLUTIFORM Inhaler?

How much to use

- Your doctor will decide what dose and what strength of FLUTIFORM Inhaler you should use, depending on the severity of your asthma.
- The usual dose is two inhalations twice a day: two in the morning and two in the evening.
- **Adolescents should not use the highest strength inhaler (FLUTIFORM Inhaler 250 micrograms/10 micrograms).**

When to use FLUTIFORM Inhaler

- FLUTIFORM Inhaler should be used twice a day (morning and night). This will help prevent asthma symptoms throughout the day and night.

Do not use FLUTIFORM Inhaler to relieve a sudden attack of breathlessness or wheezing.

How to use FLUTIFORM Inhaler

The instructions for using FLUTIFORM Inhaler are given in this leaflet. You should check with your doctor or pharmacist if you are not sure how to use FLUTIFORM Inhaler.

The medicine is contained in an aerosol can (canister) (see Diagram 1) which sits inside a plastic dispenser (also known as an actuator). The actuator has a colour-coded dose counter which displays the remaining actuations in increments of 10, down to 60 doses, and in increments of 5 thereafter. The numbers are separated by a dot. The indicator is initially green (120 to 45 puffs remaining), then yellow (45 to 25 puffs remaining), and then red (25 to 0 puffs remaining). When the indicator turns red, you should be contacting your doctor or returning to your pharmacy to have a replacement dispensed. Do not remove the canister from the actuator as this can interfere with the dose counter.



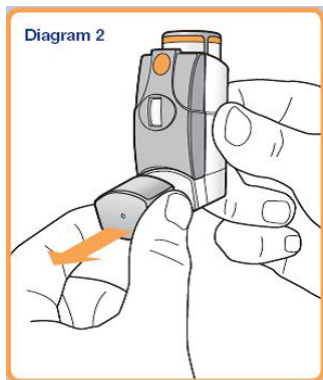
Before you use your inhaler for the first time, or if it has not been used for more than 3 days, it needs to be 'primed' to ensure it works properly and gives you the correct dose.

To 'prime' the inhaler:

- Remove the mouthpiece cover and shake the inhaler well.
- Spray away from your face by pressing down on the canister. This step should be performed 4 times.

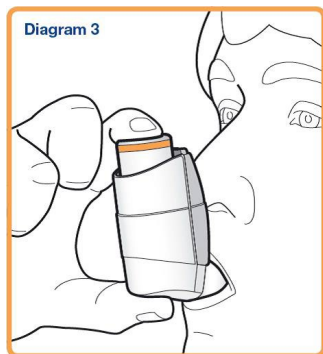
Also, in case of freezing conditions, the inhaler must be primed. Allow 30 minutes warm up to room temperature, and then spray away from your face 2 times before use.

Using your inhaler:



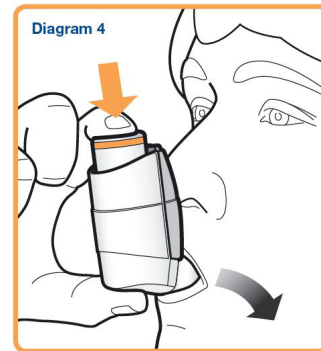
The medicine in FLUTIFORM Inhaler must only be breathed into your lungs through the mouth.

1. Remove the mouthpiece cover and check that your mouthpiece is clean and free from any dust. The inhaler should be shaken immediately before releasing each puff.
2. Sit upright or stand. Breathe out slowly and as deeply as possible.



3. Hold your inhaler upright (as shown in Diagram 3) and put the mouthpiece in your mouth with your lips around it. Do not bite the mouthpiece.

4. Breathe in slowly and deeply through your mouth and, at the same time, press down on the canister to release one puff (as shown in Diagram 4).



5. Hold your breath for as long as possible. Finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Keep the inhaler in a vertical position for about half a minute and then shake the inhaler prior to slowly repeating Steps 2 to 5.
7. Replace the mouthpiece cover.

Do not perform steps 2 to 5 too quickly.

If you see a 'mist' from the top of the inhaler or around your mouth when you use your inhaler, then you may not have inhaled your medicine properly. Have another dose by repeating from Step 2 above.

Always rinse your mouth out, gargle with water or brush your teeth after you have used your inhaler and spit out the residue.

This may help prevent you developing a hoarse voice or sore mouth, throat or tongue.

If you have weak hands, it may be easier to hold the inhaler in both hands placing both index fingers on the canister and both thumbs on the base of the inhaler.

If you have difficulty using your inhaler, your doctor may also recommend a spacer, a device to help you use your medicine properly.

Your doctor or pharmacist will advise you how to use your spacer device with your inhaler. It should also come with instructions for use and care.

Caring for your inhaler:

It is important to clean your inhaler weekly.

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the canister from the actuator as this can interfere with the dose counter.
- Wipe the inside and outside of the mouthpiece and the outside of the actuator with a clean, dry cloth or tissue.
- Replace the mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

If you have any difficulties or do not understand the instructions, talk to your doctor or pharmacist.

How long to use it

You must use your FLUTIFORM Inhaler every day (twice a day).

Do not stop using it, even if you feel better, unless your doctor tells you.

If you forget to use FLUTIFORM Inhaler

FLUTIFORM Inhaler should be used regularly at the same times each day. If you miss your dose at the usual time, use it as soon as you remember.

If it is almost time for your next dose, skip the missed dose, then use your next dose when you are meant to.

Do not use a double dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for hints. For example, use your medicine at the same time each morning and evening such as 8 a.m. and 8 p.m.

If you use too much FLUTIFORM Inhaler

If you think that you have used too much FLUTIFORM Inhaler, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you use too much of FLUTIFORM Inhaler than you should, you may experience severe chest pain (angina), high or low blood pressure, a headache, muscle cramps, difficulty in sleeping, nervousness, a dry mouth, a loss of appetite, seizures, fits or convulsions. You may feel shaky, lightheaded, faint, tired, sick or generally unwell. You may also notice changes in the rate of your heartbeat. There may be changes to potassium and sugar levels in your blood. You may also suffer from symptoms such as abdominal pain, being sick, weight loss or decreased level of consciousness (which could make you feel drowsy or confused).

If you have used more than the prescribed dose for a long period of time, you should talk to your doctor or pharmacist for advice.

When seeking medical attention, take this leaflet and your inhaler with you to show the doctor.

5. What should I know while using FLUTIFORM Inhaler?

Things you should do

Use FLUTIFORM Inhaler exactly as your doctor has prescribed.

If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.

Tell your doctor if you are going to have an operation, have had an accident or have a severe infection.

If your body is stressed, you may need other medicines.

If you are going to have an operation under a general anaesthetic, please tell the doctor at the hospital that you are using this inhaler.

Keep all of your doctor's appointments so that your progress can be checked.

Make sure you have enough doses of FLUTIFORM Inhaler with you to last over weekends and holidays.

Remind any doctor, dentist or pharmacist you visit that you are using FLUTIFORM Inhaler.

Call your doctor straight away if you:

- you are getting more breathless or wheezy
- you are using your 'reliever' medicine more than usual
- your 'reliever' medicine does not help your breathing as much as usual
- the effect of your 'reliever' medicine does not last as long as usual
- you need more doses of your 'reliever' medicine than usual to get relief.
- become pregnant while using this medicine
- for any reason, have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that your medicine was not effective and change your treatment unnecessarily.

- have used more than the prescribed dose for a long time. This is because large doses may reduce the amount of steroid hormones produced by your body.
- notice that you have a sore mouth, throat or tongue, sore, creamy-yellow, raised patches in the mouth or a hoarse voice.

These problems are less likely to happen if you use a spacer or rinse your mouth out each time after using FLUTIFORM Inhaler.

Things you should not do

Do not use FLUTIFORM Inhaler to treat an acute asthma attack (sudden attack of breathlessness or wheezing).

You will need a fast-acting 'reliever' medicine if this happens. You should carry your 'reliever' medicine with you at all times.

If you feel you are getting more breathless or wheezy more often than normal, or you are using your fast-acting 'reliever' medicine more than usual, you should talk to your doctor.

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not use FLUTIFORM Inhaler to treat any other complaint unless your doctor tells you to.

Do not give FLUTIFORM Inhaler to anyone else, even if they have the same condition as you.

Do not stop using FLUTIFORM Inhaler or change the dosage without checking with your doctor.

If you need to stop using FLUTIFORM Inhaler, your doctor will tell you how to do this. Usually, your dose will be gradually reduced each day, before stopping the medicine completely. This is to reduce the risk of triggering an asthma attack.

Driving or using machines

Be careful driving or operating machinery until you know how FLUTIFORM Inhaler affects you.

FLUTIFORM Inhaler is unlikely to affect your ability to drive or operate machinery. However, as with many other medicines, some people may experience blurred vision, dizziness or spinning sensation, light-headedness or tiredness.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may interfere with FLUTIFORM Inhaler.

Looking after your medicine

- Keep your inhaler in a cool, dry place, where the temperature stays below 25°C.
- Do not keep your inhaler in the refrigerator or freezer.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

WARNING: The canister contains a pressurised liquid. Do not puncture, break or burn the can even when apparently empty.

When to discard your medicine

Discard your medicine, if:

- your doctor tells you to stop using the inhaler
- the inhaler has been removed from the foil pouch for over 3 months
- the dose counter reads "0"
- the inhaler has passed their expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have unwanted side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Cardiovascular related:</p> <ul style="list-style-type: none">• An increase in the amount of sugar in your blood• Swelling of legs and ankles <p>Eye related:</p> <ul style="list-style-type: none">• Blurred vision or other visual disturbances <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Diarrhoea• Nausea, vomiting• Indigestion <p>Mouth related:</p> <ul style="list-style-type: none">• Changes in taste• Hoarse voice• Dry mouth• Irritated throat• Raised patches in the mouth• Sore mouth, throat or tongue <p>Musculoskeletal related:</p> <ul style="list-style-type: none">• Muscle spasms or pain• Tiredness or unusual weakness <p>Nervous system related:</p> <ul style="list-style-type: none">• Headache• Shaking or tremors• Dizziness or spinning sensation <p>Psychiatric related:</p> <ul style="list-style-type: none">• Abnormal dreams or difficulty in sleeping• Agitation or anxiety <p>Respiratory related:</p> <ul style="list-style-type: none">• Inflammation of the sinuses, runny or blocked nose	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Allergy related: <ul style="list-style-type: none">• Shortness of breath• Wheezing• Shallow or difficult breathing• Swelling of the tongue, throat, face, lips or other parts of the body• Rash, itching or hives on the skin Cardiovascular related: <ul style="list-style-type: none">• Irregular heart beat or palpitations• Chest pain Psychiatric related: <ul style="list-style-type: none">• Feeling nervous or restless• Mood changes Respiratory related: <ul style="list-style-type: none">• Worsening of your asthma (shortness of breath, coughing) Skin related: <ul style="list-style-type: none">• Bruising	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

If you get any side effects, do not stop using FLUTIFORM inhaler without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FLUTIFORM Inhaler contains

Active ingredient (main ingredient)	Each dose contains: 50 micrograms of fluticasone propionate/5 micrograms of formoterol fumarate dihydrate 125 micrograms of fluticasone propionate/5 micrograms of formoterol fumarate dihydrate
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	250 micrograms of fluticasone propionate/ 10 micrograms of formoterol fumarate dihydrate.
Other ingredients (inactive ingredients)	Sodium cromoglycate Absolute ethanol Apaflurane (HFA 227, propellant)

Do not take this medicine if you are allergic to any of these ingredients.

HFA 227 is a CFC-free propellant.

This medicine does not contain lactose, sucrose, gluten or tartrazine.

What FLUTIFORM Inhaler looks like

FLUTIFORM® Inhalers are pressurised metered-dose inhalers. The inhalers are small canisters containing a white to off-white liquid suspension fitted with a metering valve. The canisters are inserted into plastic dispensers (actuators) fitted with a dust cap and a dose indicator which indicates the number of doses remaining. Each inhaler contains 120 actuations (puffs).

They are available in three strengths:

50 micrograms/5 micrograms

125 micrograms/5 micrograms

250 micrograms/10 micrograms.

FLUTIFORM® Inhalers are packed in foil pouches within a box containing one inhaler.

Australian Registration Numbers for FLUTIFORM® pressurised inhalation:

50 micrograms/5 micrograms: AUST R 177869

125 micrograms/5 micrograms: AUST R 177873

250 micrograms/10 micrograms: AUST R 177875

Who distributes FLUTIFORM Inhaler

FLUTIFORM® pressurised inhalation is supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

10 Carrington Street

Sydney, NSW, 2000

Phone: 1800 188 009

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