

Patient Information Leaflet

Foradil® 12 microgram inhalation capsules (formoterol fumarate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

The name of your medicine is Foradil 12 microgram inhalation capsules but will be referred to as Foradil throughout this leaflet.

What is in this leaflet:

1. What Foradil is and what it is used for
2. Before you take Foradil
3. How to take Foradil
4. Possible side effects
5. How to store Foradil
6. Contents of the pack and other information

1. What Foradil is and what it is used for

The Foradil pack includes a blister pack of capsules containing the medicine and an inhaler device for taking the medicine. The capsules are for inhalation use only. Instructions for using the inhaler are given later on in the leaflet.

The active ingredient in this medicine is formoterol fumarate dihydrate. Formoterol fumarate dihydrate is one of a group of medicines called long-acting bronchodilators. It makes breathing easier by relaxing muscle spasms in the air passages of the lungs.

- Foradil is used to treat asthma in people who are already taking inhaled steroids but still have symptoms such as wheezing and breathlessness. Taking Foradil regularly together with inhaled steroids will help to prevent breathing problems
- Foradil is also used to treat breathing problems in patients with chronic obstructive pulmonary disease (COPD)

2. Before you take Foradil

Do not take Foradil if:

- you are allergic to formoterol fumarate dihydrate or any of the other ingredients of this medicine (listed in section 6).

Foradil is not suitable for children under six years of age.

Talk to your doctor or pharmacist before taking Foradil if you:

- are taking any other asthma medicine
- suffer from any heart problems
- have high blood pressure
- have an overactive thyroid gland
- have an aneurysm (area where an artery is swollen because the wall of the artery is weak)
- have a heart disorder such as abnormal electrical signal called 'prolongation of QT interval'
- are diabetic
- have pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure)

Other medicines and Foradil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly:

- Medicines for heart conditions including irregular heart beats, angina and heart failure
- Medicines for high blood pressure
- Beta blockers (either as tablets or eye drops)
- Water tablets (diuretics)
- Medicines for depression, for example, monoamine oxidase inhibitors (MAOIs) or tricyclics
- Anti-histamines or cold remedies (including any bought from the chemist)

- Medicines called 'steroids'. Your doctor will know which these are
- Sympathomimetic agents, which are adrenaline-like medicines used to treat asthma and nasal congestion
- Phenothiazines, which are a group of medicines which control mental disorders such as schizophrenia, mania, psychotic conditions and anxiety
- Xanthines, for example theophylline or aminophylline, which are a class of medicines used to treat asthma and chronic obstructive airways diseases
- Macrolides (for example Erythromycin) used to treat bacterial infections
- Anaesthetics like Halogenated hydrocarbons (for example Halothane). These drugs are used to produce anaesthesia during surgery
- Anticholinergic drugs (for example Ipratropium bromide) used to treat gastrointestinal disorders and genitourinary disorders

Other special warnings

- You must not use Foradil to treat a sudden asthma attack. Your doctor will have given you another inhaler (a 'reliever') for this
- It is very important to keep using your other asthma medicines, (inhaled steroids known as a 'preventer'), regularly. DO NOT stop using them or change the dose when you start using Foradil
- If you feel that you are getting breathless or wheezy while you are using Foradil, you should continue to use it, but go to see your doctor as soon as possible in case you need another medicine
- Treatment with Foradil may lead to your blood level of potassium becoming too low. This may make you more susceptible to abnormal heart rhythm. Therefore, your doctor may monitor your blood level of potassium, especially if you have severe asthma
- Treatment with Foradil may lead to increased sugar levels in the blood. Therefore, you might need to monitor your blood sugar levels if you are diabetic

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

In some patients, Foradil has been reported to cause dizziness. If you feel dizzy, do not drive or operate machinery.

Foradil contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Foradil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Foradil capsules must only be used with the inhaler provided. You must not try to inhale them using another inhaler. Also, do not put other types of capsules into the inhaler supplied with Foradil.

Do not swallow the capsules. The contents of the capsule must be inhaled using the inhaler provided.

For the treatment of asthma

Adults and the elderly

- **The usual dose** is 1 puff (1 capsule=1 puff) morning and evening
- The usual dose for more severe cases is 2 puffs (2 capsules) morning and evening
- You should not take more than 4 capsules in a day

Children aged 6 and over

- **The usual dose** is 1 puff (1 capsule=1 puff) morning and evening
- A child should not take more than 2 capsules in a day.

When you have asthma you must also be taking an inhaled steroid at the same time as Foradil.

For the treatment of COPD (Chronic Obstructive Pulmonary Disease)

Adults and the elderly

- **The usual dose** is 1 puff in the morning and evening

Children under 18

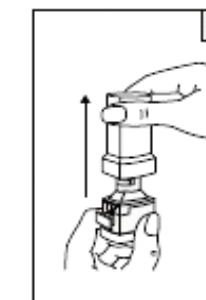
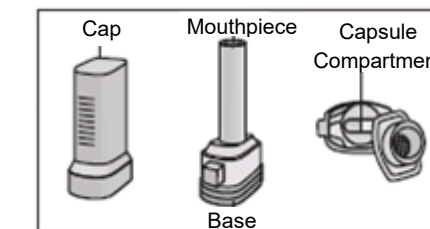
- Not applicable

The effects of this medicine will normally last for 12 hours. If you do get attacks of wheezing between doses, do not take extra doses of Foradil. Your doctor will have prescribed another medicine for this purpose. If you are not sure about this, check with your doctor.

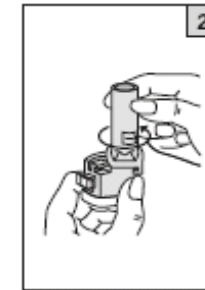
- Do not stop or reduce the dose of Foradil or any other medicine for your breathing just because you feel better, without talking to your doctor first. It is very important to use these medicines regularly
- Do not increase your dose of Foradil without talking to your doctor first
- If you feel sick or very shaky or if you have an unusually fast heart beat, your Foradil dose may be too high. Tell your doctor as soon as possible

How to use the capsules with the inhaler device

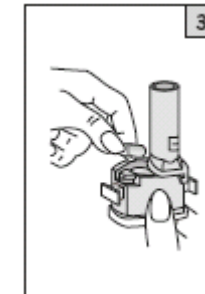
A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.



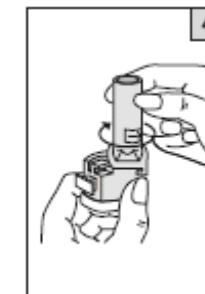
1. Pull off the cap.



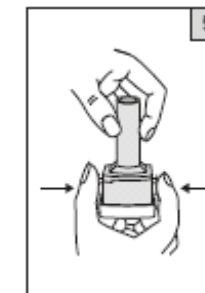
2. Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow on the bottom of the mouthpiece to open.



3. Take one of today's capsules out of the blister strip. Place it in the capsule-shaped compartment in the base of the inhaler. It is important that you remove the capsule from the blister pack **only** immediately before you use it.



4. Twist the mouthpiece to the closed position until it clicks.



5. Keeping the inhaler upright, firmly squeeze the two blue buttons **once only**. This will pierce the capsule. Release the buttons. Although the capsule is now pierced, the powder will not be released until you inhale it.



6. Breathe out fully.



7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs.

You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, the capsule may be stuck in the compartment. If this occurs, open the inhaler and loosen the capsule by prising it out of the compartment. **Do not** try to loosen the capsule by repeatedly pressing the buttons.

8. If you have heard the whirring noise, **hold your breath** for as long as you comfortably can while taking the inhaler out of your mouth. Then breathe normally. Open the inhaler to see if any powder is still in the capsule. If there is still powder in the capsule repeat steps 6 to 8.
9. After use, tip out the empty capsule and close the mouthpiece.
10. Replace the cap.
11. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a **dry** cloth or a clean soft brush.

Very occasionally, very small pieces of the capsule shell can get in the mouth. If this happens, you may be able to feel these pieces on your tongue. The capsule shell is made of gelatin which is harmless to humans, and will soften or dissolve in the mouth and be swallowed. The chances of this happening will be increased if the capsule is pierced many times (Step 5); hence it is recommended that you do this only once for each capsule.

If you forget to take Foradil

If you miss a dose, take it as soon as you remember. Then go on as before. Do not double the dose to make up for the forgotten dose.

What if you take too much?

If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department immediately. Take your medicine pack with you so that people can see what you have taken.

4. Possible side effects

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

Some side effects can be serious
Stop using Foradil and tell your doctor straight away if you notice:

- Bronchospasm with wheezing or coughing and difficulty in breathing. This may affect up to 1 in 100 people
- An allergic reaction such as if you feel faint (you might have low blood pressure), have a rash, or experience itching or facial swelling. This may affect up to 1 in 1,000 people
- If you feel you have muscle weakness, muscle spasms or an abnormal heart rhythm (these could mean you have a low blood potassium level). This may affect up to 1 in 1,000 people
- If you feel you have an irregular heart beat or a fast heart beat. This may affect up to 1 in 1,000 people
- If you feel a crushing chest pain (symptoms of angina pectoris). This may affect up to 1 in 10,000 people.

The side effects listed below have also been reported.

Common (may affect up to 1 in 10 people)

Headache, tremor, palpitations.

Uncommon (may affect up to 1 in 100 people)

Agitation, anxiety, feeling nervous, difficulties with sleeping, dizziness, fast heart beat, throat irritation, dry mouth, muscle cramps, muscle pain, worsening of asthma.

Rare (may affect up to 1 in 1,000 people)

Nausea

Very rare side effects (may affect up to 1 in 10,000 people)

Distorted sense of taste, swelling of hands, ankles or feet, variations in blood pressure. Excessive thirst, frequent urination and tiredness over an extended period of time (a possible indication of high blood sugar).

Not known (frequency cannot be estimated from the available data)

Headache and dizziness (symptoms of high blood pressure), cough and rash. Some of these effects may wear off as you get used to the medicine.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting any side effects, you can help provide more information on the safety of this medicine.

5. How to store Foradil

Keep out of the sight and reach of children. Do not store above 25°C. Protect from moisture and heat.

Do not take the capsules out of the blister pack until you need them.

Do not take the capsules after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the capsule becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active ingredient in this medicine is formoterol (as formoterol fumarate dihydrate). This is the new name for eformoterol. The ingredient itself has not changed. Foradil comes as capsules containing a dry powder for inhalation. Each capsule contains 12 micrograms of formoterol fumarate dihydrate. This is one of a group of medicines called bronchodilators. The other ingredient is lactose monohydrate.

Foradil comes as a clear capsules marked with 'CG' and 'FXF' in black ink containing white dry powder for inhalation. They come with a light blue and white inhaler device. The dry powder is inhaled into the lungs using the inhaler provided in the pack.

Foradil comes in blister packs of 60 inhalation capsules with inhaler.

Manufactured by: Novartis Farma S.p.A., Viale Luigi Sturzo 43, 20154 Milan MI, Italy.
OR

Novartis Farma S.p.A., Largo Umberto Boccioni 1, Origgio (VA), Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Foradil® 12 microgram inhalation capsules; PL 18799/1227

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Foradil is the registered trademark of Sandoz AG.

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