

Package leaflet: Information for the user

Foradil® Aerolizer® 12 microgram inhalation powder, hard capsules formoterol fumarate dihydrate

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. 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.

What is in this leaflet

1. What Foradil is and what it is used for
2. What you need to know before you use Foradil
3. How to use 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 a special inhaler device called an Aerolizer for taking the medicine. Instructions for using the inhaler are given later on in the leaflet. The active substance in this medicine is formoterol fumarate dihydrate. This 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.
- for the prevention of breathing problems brought on by exercise, cold air or breathing in something that you are allergic to
- to treat breathing problems in patients with chronic obstructive pulmonary disease (COPD), chronic bronchitis and emphysema.

2. What you need to know before you use Foradil

Do not use Foradil

- if you are allergic (hypersensitive) to formoterol or to lactose (which contains small amounts of milk proteins) or any of the other ingredients of this medicine (listed in section 6).
- if you have a rare problem digesting sugars called “galactose intolerance”, “total lactase deficiency” or “glucose-galactose malabsorption”. This runs in families.

Do not use Foradil if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Foradil.

Warnings and precautions

Talk to your doctor or pharmacist before using Foradil

- if you are a child between 6 and 12 years of age.
- if you have asthma and this is the only breathing medication you are taking. Foradil should only be used in people with asthma who are already taking a steroid inhaler.

- if you have high blood pressure.
- if you have heart problems.
- if you have an overactive thyroid gland.
- if you are diabetic. 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.
- if you have an aneurysm (area where an artery is swollen like a sack because the wall of the artery is weak).
- if you have phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure).
- if you have a heart disorder, such as abnormal electrical signal called “prolongation of the QT interval”.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Foradil.

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 taking your other asthma medicines such as inhaled steroids (a “preventer”), regularly. Do not stop taking them or change the dose when you start taking Foradil.
- If you feel that you are getting breathless or wheezy while you are taking Foradil, you should continue to take it, but go to see your doctor as soon as possible in case you need another medicine.
- **Do not swallow the capsules - they must be used by inhaling the content of the capsule with the Aerolizer inhaler.**
- Treatment with Foradil may lead to your blood level of potassium becoming too low. This may make it more likely for you to have an abnormal heart rhythm. So your doctor may monitor your blood level of potassium, especially if you have severe asthma.

Children and adolescents

This medicine is not recommended for use in children under 6 years of age.

Other medicines and Foradil

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines.

In particular, tell your doctor if you are taking any of the following medicines:

- beta blockers (either as tablets or eye drops), which are a type of medicine used to treat high blood pressure, heart failure, angina, anxiety and abnormal heart rhythm. Certain eye drops used to treat glaucoma may contain beta blockers.
- water tablets (diuretics), which are used to treat oedema (water retention), heart failure and high blood pressure.
- macrolide antibiotics such as erythromycin or azithromycin, which are used to treat bacterial infections.
- sympathomimetic agents, which are adrenaline-like medicines used to treat asthma and nasal congestion.
- quinidine, disopyramide, and procainamide, which are medicines used to treat abnormal heart rhythm.
- phenothiazine derivatives, which are a group of medicines which control mental disorders such as schizophrenia, mania, psychotic conditions and anxiety.
- digitalis, a medicine used to treat heart failure and abnormal heart rhythm.
- medicines for depression or mood problems for example monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants or “phenothiazines”.
- antihistamines, which are common anti-allergy medicines used to prevent or treat the major symptoms of an allergic response eg. terfenadine, astemizole and mizolastine.
- theophylline or aminophylline used to treat asthma and COPD.
- steroids, which are often used to treat asthma and other inflammatory problems.
- inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform

your doctor that you use Foradil if you are to have surgery under anaesthesia.

- anticholinergic drugs (e.g. Ipratropium bromide) used to treat gastrointestinal disorders, genitourinary disorders etc.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Foradil.

Operations and tests

Tell your doctor if you are going to have an operation. This is because some medicines given to you during the operation (inhaled anaesthetics e.g. halothane) can affect your heart if you are also taking Foradil.

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 for advice before taking this medicine. You should not use Foradil unless your doctor tells you to do so.

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

This medicine contains lactose (a type of sugar). 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 use Foradil

Follow your doctor's instructions carefully. Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to use the Aerolizer. Do not exceed the recommended dose. **Do not swallow the capsules. The capsules should be used by inhaling the content with the Aerolizer inhaler.** Keep taking the inhaler for as long as you have been told unless you have any problems. In that case, check with your doctor.

How much Foradil to use

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.
- If your regular dose is 1 puff (1 capsule) twice a day, you may also use 1 or 2 extra puffs (1 or 2 extra capsules) during the day for relief of ordinary symptoms in addition to the regular dose, but only if necessary. However if you feel you need to use these extra capsules more than 2 days a week you should tell your doctor as soon as possible because it may be that your condition is getting worse.

Children aged 6 and over

- **The usual dose** is 1 puff (1 capsule = 1 puff) morning and evening.

The use of Foradil is not recommended in children under the age of 6.

When you have asthma you will also be taking an inhaled steroid at the same time.

For the prevention of breathing problems caused by exercise, cold air or breathing in something that you are allergic to

Adults, the elderly and children aged 6 and over

- **The usual dose** is 1 puff (1 capsule = 1 puff) at least 15 minutes before exercise or exposure. If you are an adult, in some cases, your doctor may advise you to use 2 puffs (2 capsules) in this situation.

For the treatment of COPD (Chronic Obstructive Pulmonary Disease)

Adults and the elderly

- **The usual dose** is 1 to 2 puffs (1 capsule = 1 puff) morning and evening.

Do not increase your dose 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.

The instructions for using the inhaler are given later on in this leaflet. A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.

If you forget to use Foradil

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

If you use more Foradil than you should

Tell your doctor straight away or go your nearest hospital casualty department if you, or anyone else, accidentally takes too much of this medicine. Take your medicine pack with you so that people can see what you have taken. You may feel sick or have to vomit, you may experience headaches, trembling, dizziness (possible symptoms of high blood pressure), a fast heart beat or sleepiness.

If you stop using Foradil

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.

4. Possible side effects

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

Some side effects may be serious. Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Uncommon: *may affect up to 1 in every 100 people*

- bronchospasm with wheezing or coughing and difficulty in breathing.

Very rare: *may affect up to 1 in every 10,000 people*

- feel faint (you might have low blood pressure), have a rash, or experience itching or facial swelling. These might be the result of an allergic reaction.

Not known: *frequency cannot be estimated from the available data*

- muscle weakness, muscle spasms or an abnormal heart rhythm (these symptoms could mean you have a low blood potassium level)
- crushing chest pain (possible sign of angina pectoris)
- irregular heart beat (including fast heart beat)

Other side effects may include:

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Common: *may affect up to 1 in every 10 people*

- headache
- involuntary shaking movement (tremor)
- unusual pounding or irregular heart beat (palpitations)
- worsening of asthma in children aged 5 to 12 years

Uncommon: *may affect up to 1 in every 100 people*

- agitation

- anxiety
- feeling nervous
- difficulties with sleeping
- dizziness
- fast heart beat
- throat irritation
- muscle cramps or muscle pain
- dry mouth

Rare: *may affect up to 1 in every 1,000 people*

- nausea

Very rare: *may affect up to 1 in every 10,000 people*

- distorted sense of taste
- swelling of hands, ankles and feet
- variations in blood pressure

Not known: *frequency cannot be estimated from the available data*

- excessive thirst, frequent urination and tiredness over an extended period of time (a possible indication of high blood sugar).
- raised blood pressure
- cough
- rash

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist. They may want to give you a different medicine.

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Foradil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Always discard the old Aerolizer inhaler and use the new one provided with each new pack.

6. Contents of the pack and other information

What Foradil contains

- The active substance is formoterol fumarate dihydrate. Each hard gelatin capsule of Foradil inhalation powder contains 12 micrograms of formoterol fumarate.
- The other ingredients are lactose monohydrate (25 mg per capsule which contains milk proteins) and

gelatin.

What Foradil looks like and contents of the pack

- The capsules are colourless and see-through with the markings “CG” on one part and “FXF” on the other part of the capsule.
- The pack contains an inhaler and 6 blister packs each containing 10 capsules.

Marketing Authorisation Holder

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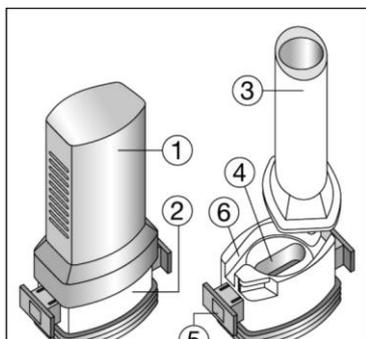
INSTRUCTIONS FOR USE

Read these instructions carefully so that you know how to use this medicine.

How to use Foradil with your Aerolizer inhaler

Please read the following instructions carefully to learn how to take the Foradil capsules with the Aerolizer inhaler.

- Use the Foradil capsules only with the Aerolizer inhaler provided in the pack. Do not use a different type of inhaler.
- Do not swallow the capsules. The powder in the capsules is for you to breathe in.

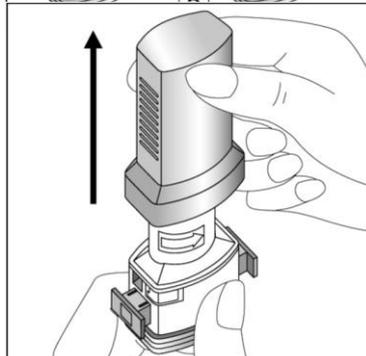


The Aerolizer is made up of two parts:

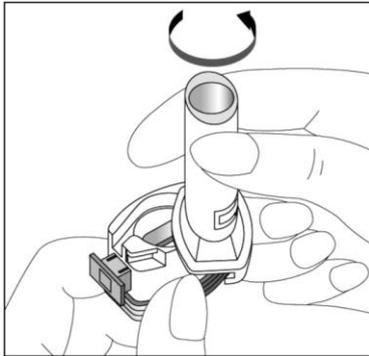
1. A blue cap to protect the mouthpiece.
2. A base.

The base is made up of:

3. A mouthpiece.
4. A capsule chamber.
5. A blue button with “winglets” and pins on each side.
6. A channel to let the air in.



1. Pull off the cap.

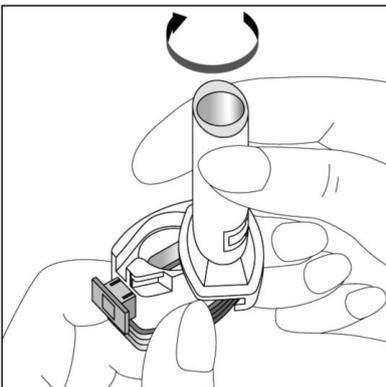


2. Hold the base firmly and turn the mouthpiece in the direction of the arrow (anti-clockwise). This opens the capsule chamber.

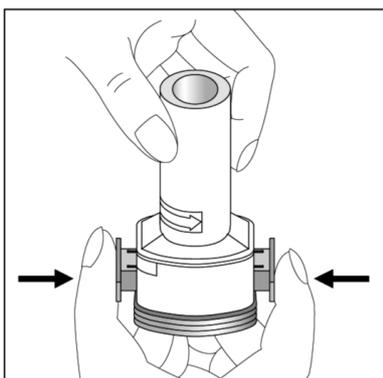


3. Remove one capsule out of the blister strip and place it flat into the capsule chamber:

- Make sure your fingers are completely dry.
- Only remove a capsule from the blister pack when you are ready to use it.
- Do not put the capsule into the mouthpiece.



4. Close the capsule chamber by turning the mouthpiece back until you hear a “click”.

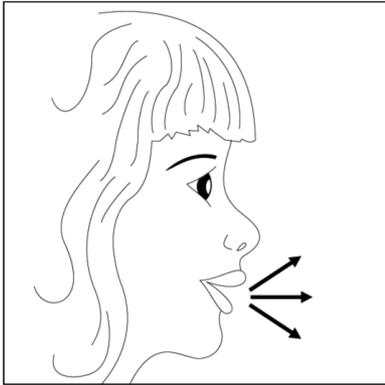


5. To release the powder from the capsule:

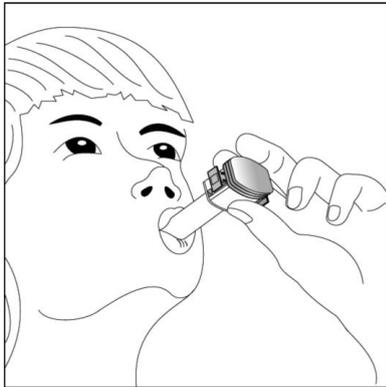
- Hold the Aerolizer in the upright position with the mouthpiece pointing up.
- Pierce the capsule by firmly pressing together both blue side buttons at the same time. Then release the buttons. Do this only once.
- If the buttons get stuck then gently pull them back into their starting position with the help of the “winglets”.

The capsule may break up when you do this and small gelatin pieces might get into your mouth or throat. You can

swallow the pieces and they are not harmful.



6. Breathe out fully.



7. To breathe your medicine deeply into your airways:

- Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips firmly around the mouthpiece.
- Breathe in rapidly but steadily and as deeply as you can.
- You should hear a whirring noise as the capsule spins around in the space above the capsule chamber. If you do not hear this noise, open the capsule chamber (see step 2) and check that the capsule lies loose in the capsule chamber
- Do not try to loosen the capsule by repeatedly pressing the side buttons.

- If the capsule is jammed then turn the open capsule chamber upside down and gently tap the bottom. Then

repeat step 7.

- You will have a sweet taste in your mouth from the lactose and you may feel powder at the back of your throat. This is normal.

8. After breathing in:

- Hold your breath for as long as you comfortably can while taking the inhaler from your mouth.
- Then breathe out through your nose.
- Open the capsule chamber to see if there is any powder left in the capsule. If there is, repeat steps 6 to 8.

9. After you have used up all the powder, open the capsule chamber (see step 2).

- Remove the empty capsule and use a dry tissue or a soft brush to remove any powder left inside.
- Do not use water to clean the inhaler.

10. Close the capsule chamber and replace the cap.