

FORADIL[®]

Eformoterol fumarate dihydrate

12 mcg inhalation capsules

What is in this leaflet

This leaflet answers some common questions about Foradil.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Foradil is used for

Foradil is inhaled into the lungs for the treatment of asthma. Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke or other irritants.

Foradil is also used to treat chronic obstructive pulmonary disease, also called COPD. This is a serious lung condition that can cause difficulty in breathing, wheezing and constant coughing.

Foradil belongs to a group of medicines called bronchodilators. These medicines are used to keep the air passages in the lungs open.

Foradil is a long acting bronchodilator. It is used for people who need to take medicine every day for their asthma. Foradil is used together with other medicines called corticosteroids.

Foradil contains the active ingredient, eformoterol fumarate dihydrate, in a capsule form. Foradil capsules are for oral inhalation only. The powder from the capsule is inhaled (breathed into the lungs) using the Aerolizer[®] inhalation device provided with the medicine.

Each dose of Foradil will keep your air passages open and relieve chest tightness and wheezing for up to 12 hours. It is especially helpful if you have breathing problems during exercise or at night.

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

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription. It is not addictive.

Before you use Foradil

When you must not use it

Do not use Foradil if you have ever had an allergic reaction after using:

- eformoterol fumarate dihydrate (the active ingredient in Foradil)
- any of the other ingredients listed at the end of this leaflet

You may get a skin rash, difficulty in breathing, hay fever, swelling of the face, faintness or other symptoms if you use it.

Do not use Foradil to relieve acute attacks of asthma.

Your doctor will have given you a "reliever puffer" to use when you have a sudden problem with breathing. Carry that medicine with you at all times.

Do not use Foradil if you:

- are well controlled with an inhaled corticosteroid,
- only need short-acting beta₂-agonist medicines once in a while.

Do not give Foradil to children under 6 years of age.

There is not enough experience to recommend its use in children under 6 years of age.

Do not use Foradil after the use by (expiry) date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well as it should.

Do not use Foradil if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should start using Foradil, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have any of these medical conditions:

- a heart problem
- diabetes
- an overactive thyroid gland

Your doctor may want to take special precautions if you have any of these conditions.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes.

Foradil contains lactose (milk sugar). If you have severe lactose intolerance, tell your doctor before taking Foradil.

Talk to your doctor about the benefits and possible risks of treating your asthma with Foradil.

A large study with a different long-acting bronchodilator (salmeterol) showed an increase in the risk of death due to asthma compared to the risk in patients who used a placebo (dummy) puffer. No study has been done to find out if Foradil could have the same effect.

If you have asthma: Do not use Foradil as your only asthma medicine. Use Foradil only with an inhaled corticosteroid (ICS).

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

Foradil is not recommended for use during pregnancy. If it is necessary for you to use Foradil, your doctor will discuss with you the benefits and risks of using it during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not known if the active ingredient of Foradil passes into the breast milk and could affect your baby.

If you have not told your doctor about any of these things, tell him/her before you start using Foradil.

Taking other medicines

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

Some medicines and Foradil may interfere with each other. These include medicines used to treat:

- high blood pressure
- heart problems, heart failure, abnormal heart rhythm
- depression (sad mood), schizophrenia, mania, psychotic conditions and anxiety
- glaucoma (including eye drops)
- allergies like hay fever
- coughs and colds
- asthma, chronic obstructive airways disease and nasal congestion

These medicines may be affected by Foradil or they may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are using Foradil.

How to use Foradil

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to use

For Asthma:

Adults: the usual dose is 1 or 2 capsules inhaled twice a day. The maximum recommended dose per day for adults is 4 capsules. In some cases this may vary depending on your doctor's instructions.

For asthma therapy, you will always be prescribed Foradil in addition to an ICS.

Children 6 years and over: the usual dose is 1 capsule inhaled twice a day. The maximum recommended dose per day for children is 2 capsules.

For COPD:

The usual dose is 1 capsule inhaled twice a day.

When to use it

The doses are usually inhaled about 12 hours apart (eg. in the morning and evening) so that your breathing problems are relieved for the whole day and night.

How to use the Aerolizer

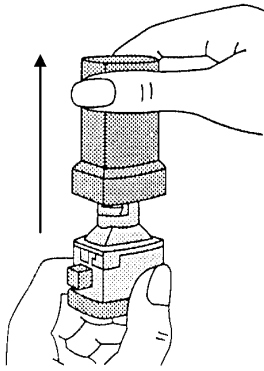
Use the capsules only with the Aerolizer inhalation device provided in the pack. Do not swallow the capsules.

Follow the instructions and pictures which show you how to use the inhalation device.

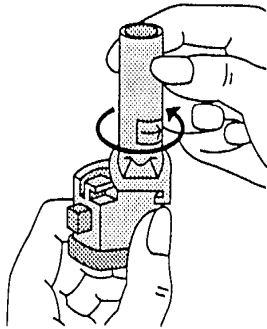
Children should only use the device with the help of an adult. At times small children may have trouble breathing in strongly enough to get all of the dose out of the capsule.

If you are not sure how to use the device, ask your doctor or pharmacist.

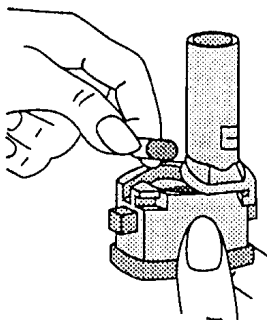
Follow these steps:



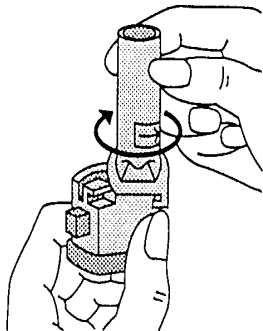
1. Pull off the cap of the Aerolizer inhalation device.



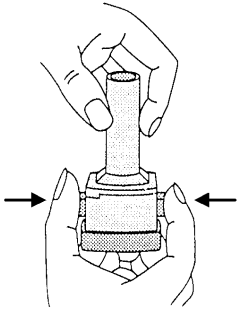
2. Hold the base of the device firmly and open it by turning the mouthpiece in the direction shown by the arrow.



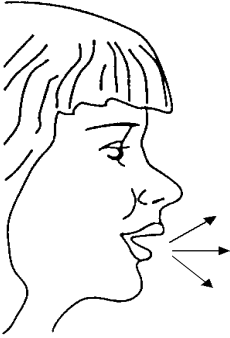
3. Making sure your fingers are completely dry, take the capsule out of the foil pack immediately before you are going to use it. Place the capsule in the capsule-shaped slot, making sure that it lies flat and on the bottom.



4. Twist the mouthpiece to the closed position.



- To pierce the capsule, hold the Aerolizer upright and firmly squeeze the two blue buttons at the same time and then release. **Pierce the capsule only once.** If you pierce it more often, the capsule may break and small pieces of gelatin from the capsule shell may be inhaled into your mouth or throat. However the capsule is made of edible gelatin, which is not harmful.



- While holding the Aerolizer in an upright position, open the mouthpiece again and make sure that the capsule is loose in the slot so that when you inhale, the capsule is able to spin around in the circular area above the slot. Close the mouthpiece.
- Breathe out as far as you can.



- Place the mouthpiece in your mouth and tilt your head back slightly. Close your lips around the mouthpiece and breathe in quickly but evenly, as deep as you can.
- Hold your breath for as long as you comfortably can. Take the Aerolizer out of your mouth, then breathe out.
- Open the Aerolizer and check whether there is any powder left in the capsule. If there is, repeat steps 7 to 9.
- After using the Aerolizer, take out the empty capsule. Check the Aerolizer to see if there is any dry powder remaining in the device. To remove any remaining powder, wipe the mouthpiece and capsule slot with a dry cloth or a clean soft brush. Do not use water to clean the device. Then close the mouthpiece and put the cap on again.

Each time you get a new prescription, discard the old Aerolizer and use the new one provided in the pack.

How long to use it

Continue to use Foradil for as long as your doctor tells you to.

If Foradil helps your breathing problems, your doctor may want you to keep using it for quite a long time. This medicine helps to control your condition but it does not cure it.

If you forget to use it

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

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or National Poisons Information Centre, Dunedin (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have used too much Foradil. Do this even if there are no signs of discomfort or poisoning.

If you use too much Foradil, you may feel sick or vomit, feel shaky or sleepy, have a headache or a fast or irregular heartbeat.

While you are using Foradil

Things you must do

Use Foradil exactly as your doctor has prescribed. Try not to miss any doses and use the medicine even if you feel well.

If you do not follow your doctor's instructions, you may not get relief from your breathing problems or you may have unwanted side effects.

If you find that the usual dose of Foradil is not giving as much relief as before, or does not last as long as usual, contact your doctor so that your condition can be checked.

This is important to ensure your asthma is controlled properly.

Visit your doctor regularly to check on your condition.

Your doctor will want to check on your progress regularly.

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

This medicine is only one part of a general plan to help you manage your condition.

If you become pregnant while using Foradil, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Foradil.

Tell any other doctor, dentist or pharmacist who treats you that you are using Foradil.

Things you must not do

Do not use Foradil to relieve acute attacks of asthma. If you become wheezy or tight in the chest before the next dose of Foradil is due, use a "reliever puffer" in the usual way.

Your doctor will have given you a "reliever puffer" to use when you have a sudden problem with breathing. Carry that medicine with you at all times.

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

Do not stop any of your medicines or lower the dosage even if you feel much better.

It is very important to keep your breathing problems under control. Your doctor can only do this if you follow instructions carefully.

Do not use Foradil to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Foradil affects you.

This medicine may cause dizziness in some people. Make sure you know how you react to Foradil before you drive a car, operate machinery, or do anything else that could be dangerous. If you are dizzy, do not drive. If you drink alcohol, dizziness could be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Foradil.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- trembling or shakiness
- muscle aching or cramps
- palpitations (feeling that your heartbeat is unusually fast or irregular)
- headache
- dizziness
- feeling anxious, nervous or upset
- being unable to sleep
- sore mouth or throat from inhaling the powder in the capsule
- changed sense of taste
- nausea (feeling sick)
- dry mouth

- excessive thirst, frequent urination and tiredness over an extended period of time

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- your breathing problems suddenly become worse after having a dose of Foradil
- you develop symptoms of an allergic reaction, such as severe dizziness or fainting (caused by very low blood pressure); red itchy skin rash (hives); swelling of the face, lips, tongue, eyelids or other parts of the body.
- muscle weakness, spasms, or an abnormal heart rhythm

You may need urgent medical attention.

In some clinical studies with Foradil, serious asthma attacks (severe increase in shortness of breath, cough, wheezing, or chest tightness which can result in hospitalisation) have been observed.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Foradil

Storage

- Keep your capsules in the foil packs inside the cardboard carton until it is time to use them.
- Store the capsules in a cool dry place.
- Do not store Foradil or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. Foradil will keep well if it is cool and dry.

Keep the capsules where children cannot reach them.

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

Disposal

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

If your doctor tells you to stop using Foradil or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What it looks like

Foradil: clear capsule with one half marked CG and the other half marked FXF, in foil packs in a cardboard carton containing 60 capsules. A blue and white plastic Aerolizer inhalation device is also supplied in the pack.

Ingredients

Foradil capsules are made of gelatin, an edible material. Each capsule contains 12 micrograms of eformoterol fumarate dihydrate as the active ingredient. The capsules also contain lactose.

Sponsor

Foradil is supplied in New Zealand by:

Novartis New Zealand Limited

Private Bag 65904

Mairangi Bay

Auckland

Building G, 5 Orbit Drive

Rosedale

Auckland 0632

Telephone 0800 652 422

Date of preparation

This leaflet was prepared on 22 June 2010 based on the current data sheet for this product.

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