

Foradile[®]

capsules for inhalation

eformoterol fumarate dihydrate is now known as formoterol fumarate dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Foradile capsules.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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 Foradile is used for

Foradile capsules for inhalation belong to a group of medicines called bronchodilators. These medicines are

used to keep the air passages in the lungs open.

Foradile capsules for inhalation contain the active ingredient, formoterol fumarate dihydrate in a capsule form.

Foradile capsules make breathing easier by opening the small air passages in the lungs and helping them to remain relaxed and open.

Foradile is a long acting bronchodilator. Each dose of Foradile 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.

The 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. Foradile capsules are for the treatment of asthma and chronic obstructive pulmonary disease, also called COPD.

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.

COPD is a serious lung condition that can cause difficulty in breathing, wheezing and constant coughing.

Foradile capsules for inhalation are used for people who need to take medicine every day for their asthma. Foradile is always used together with other medicines called inhaled

corticosteroids (also known as "preventer" medicines.)

Ask your doctor if you have any questions about why Foradile 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 Foradile

When you must not use it

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

- formoterol fumarate dihydrate (the active ingredient in Foradile)
- 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 Foradile to relieve sudden wheezing or other 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 Foradile if you:

- are well controlled with an inhaled corticosteroid,

- only need short-acting beta2-agonist medicines once in a while.

Do not give Foradile to children under 5 years of age.

There is not enough experience to recommend its use in children under 5 years of age.

Do not use Foradile 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 Foradile 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 Foradile, contact your doctor or pharmacist.

Before you start to use it

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

- a heart disorder called "prolongation of the QT interval"
- any other heart problem
- aneurysm (area where an artery is swollen like a balloon because the wall of the artery is weak)
- pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure)
- 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:

- lactose (milk sugar)
- any other medicines
- any other substances such as foods, preservatives or dyes.

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

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 conducted to find out if Foradile could have the same effect.

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

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

Foradile is not recommended for use during pregnancy. If it is necessary for you to use Foradile, 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 Foradile 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 Foradile.

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 Foradile may interfere with each other. These include any of the following medicines:

- monoamine oxidase inhibitors (MAO inhibitors) or tricyclic antidepressants, which are types of medicines used to treat depression (sad mood)
- sympathomimetic agents, which are adrenaline-like medicines used to treat asthma and nasal congestion.
- antihistamines, which are common anti-allergy medicines used to prevent or treat the major

symptoms of an allergic response and hay fever

- steroids, which are often used to treat asthma and other inflammatory diseases
- diuretics, which are used to increase the amount of urine produced to treat oedema (water retention), heart failure and high blood pressure
- beta blockers, 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 (high pressure in the eye) may contain beta blockers.
- quinidine, disopyramide, and procainamide, which are medicines used to treat abnormal heart rhythm
- phenothiazine derivatives, which are a group of medicines used to control mental disorders such as schizophrenia, mania, psychotic conditions and anxiety, and mood disorders
- digitalis, a medicine used to treat heart failure and abnormal heart rhythm
- xanthine derivatives, which are a class of medicines used to treat asthma and chronic obstructive airways diseases.
- macrolide antibiotics (e.g. erythromycin; azithromycin)
- inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform your doctor that you use Foradile if you are to have surgery under anaesthesia.

These medicines may be affected by Foradile or they may affect how well Foradile works. Your doctor may need to change the dose of your medicines or may ask you to take different medicines.

If you are not sure if you are taking any of these 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 Foradile.

Your doctor may have given you other medicines to take regularly for your lung condition. If so, it is important that you:

- **continue to take these regularly**
- **DO NOT STOP or reduce the dose even if you feel much better.**

How to use Foradile

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

Always use the Foradile Aerolizer exactly as your doctor or pharmacist has told you. Ask one of them for advice if you are not sure how to use the Aerolizer.

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

Your doctor will tell you how often to use Foradile and how much to take, depending on your needs.

If you are aged 65 years or over, you can use Foradile at the same dose as other adults.

1. For Asthma

Adults

The usual dose is 1 or 2 capsules inhaled twice a day.

The maximum recommended adult dose is 4 capsules for inhalation per day.

For asthma therapy, you will always be prescribed Foradile in addition to an inhaled corticosteroid (ICS).

Tell your doctor if you need to use any extra capsules more than 2 days a week, as soon as possible,

because it may be that your condition is getting worse.

Children 5 years and over

The usual dose is 1 capsule inhaled twice a day.

The maximum recommended dose per day for children aged 5 years or older is 2 capsules.

2. For chronic obstructive pulmonary disease (COPD)

Adults

The usual maintenance dose is 1 capsule inhaled twice a day.

When to use it

Usually the doses are 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.

This Aerolizer has been specially developed for use with Foradile capsules only.

Follow the instructions and pictures inside the carton 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 the entire 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. To open the capsule chamber, hold the base of the device firmly and turn the mouthpiece in the direction shown by the arrow.
3. Make sure your fingers are completely dry, so that the capsule does not get wet. Remove the capsule from the foil pack

immediately before you are going to use it.

4. Do not swallow the capsule.

The capsule should be used by inhaling the content with the Aerolizer inhaler.

5. Place the capsule flat on the bottom of the capsule-shaped slot.
6. Close the capsule chamber by twisting the mouthpiece back until you hear the "click" at the closed position.
7. 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.

Note that 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 gelatin is edible and is not harmful.

8. 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.
9. Close the mouthpiece.
10. Breathe out fully (as far as you can).
11. Place the mouthpiece in your mouth and tilt your head slightly backwards.
12. Close your lips firmly around the mouthpiece and then breathe in quickly but evenly, as deep as you can. Note that 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 and check that the capsule lies loose in the capsule chamber. Then repeat step 11. **DO NOT** try to loosen the capsule by pressing the buttons repeatedly.

13. After breathing in through the Aerolizer, hold your breath for as long as you comfortably can.
14. Take the Aerolizer out of your mouth, and then breathe out through your nose.
15. Open the capsule chamber to check whether there is any powder left in the capsule. If there is, repeat steps 10 to 15.
16. After you have used up all the powder in the Aerolizer, open the capsule chamber and remove the empty capsule.
17. Check the Aerolizer to see if there is any dry powder remaining in the device.
18. 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.

19. Close the mouthpiece and put the cap on again.

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

How long to use it

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

If Foradile 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 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 Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much Foradile. Take the medicine pack with you.

Do this even if there are no signs of discomfort or poisoning.

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

While you are using Foradile

Things you must do

Use Foradile 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 have been prescribed Foradile for asthma, continue using your "preventer" medicine unchanged after you start using Foradile.

It should be used with a "preventer" medicine, even if you feel that your symptoms have improved.

If you find that the usual dose of Foradile 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. Treatment with Foradile may lead to lowering of your blood potassium level. This may make you more susceptible to an abnormal heart beat. Therefore, your doctor may monitor your blood potassium level, especially if you have severe asthma.

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 Foradile, 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 Foradile.

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

Things you must not do

Do not use Foradile to relieve acute attacks of asthma. If you become wheezy or tight in the chest before the next dose of Foradile 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 use other medicines that contain long-acting beta2-agonists such as salmeterol, when you are taking Foradile.

Do not stop taking any other medicines you have been given for your asthma, even if you are feeling better, without checking with your doctor first.

Foradile is intended to be used with "preventer" medicines. It is very important to keep your breathing problems under control. Your doctor

can only do this if you follow instructions carefully.

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 change or stop any of your medicines to control or treat your breathing problems including your inhaled corticosteroid.

Your doctor will adjust your medicines as needed.

Do not use Foradile 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 Foradile affects you.

This medicine may cause dizziness in some people. Make sure you know how you react to Foradile 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 Foradile.

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

The above side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following serious side effects:

- an irregular heart beat
- excessive thirst, frequent urination and tiredness over an extended period of time (a possible indication of high blood sugar)
- tight chestedness or breathing problems, with wheezing or coughing and difficulty in breathing
- sudden worsening of breathing problems after having a dose of Foradile
- muscle weakness, muscle spasms, or an abnormal heart rhythm (these could mean you have a low blood potassium level).
- 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.

You may need urgent medical attention.

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.

Some side effects, such as a low level of potassium in the blood, may only be found when your doctor orders blood tests from time to time.

After using Foradile

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 at or below 25°C.
- Do not store Foradile 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. Foradile 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 Foradile 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

Foradile: clear capsule containing a fine, white powder; one half of the capsule shell is marked CG and the

other half is marked FXF. The capsules come in foil packs containing 60 capsules in a cardboard carton.

A blue and white plastic Aerolizer inhalation device is also supplied in the pack.

Ingredients

Active Ingredient

Each capsule contains 12 micrograms of formoterol fumarate dihydrate.

Inactive ingredients

Foradile capsules also contain lactose. The capsule shell is made of gelatin, an edible material.

Sponsor

Foradile is supplied in Australia by:

NOVARTIS Pharmaceuticals

Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1800 671 203

® = registered trademark

This leaflet was prepared in November 2016.

Australian Registration Number

AUST R 58673

(CMI for251116c.doc based on PI for251116i.doc)