

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 Foradile?

Foradile contains the active ingredient formoterol (eformoterol) fumarate. Foradile is used to keep the air passages in the lungs open.

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

2. What should I know before I use Foradile?

Do not use if you have ever had an allergic reaction to formoterol (eformoterol) fumarate 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 Foradile?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Foradile 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 Foradile?

- Your doctor will tell you how often to use Foradile and how much to take, depending on your needs.
- Always use the Foradile Aerolizer exactly as your doctor or pharmacist has told you.

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

5. What should I know while using Foradile?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Foradile.• Use Foradile exactly as your doctor has prescribed.• If you have been prescribed Foradile for asthma, continue using your "preventer" medicine unchanged after you start using Foradile.• If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times
Things you should not do	<ul style="list-style-type: none">• 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.• Do not use other medicines that contain long-acting beta-2-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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Foradile affects you.
Looking after your medicine	<ul style="list-style-type: none">• 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.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include trembling or shakiness, muscle aching or cramps, fast/irregular heart rate, headache, dizziness, being unable to sleep, sore mouth or throat, nausea or taste disturbances. However, some side effects may need medical attention. These include severe allergic reactions such as difficulty breathing, swelling of the face, lips or tongue or severe rash. Serious side effects are rare.

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.

Foradile®

Active ingredient(s): *formoterol (eformoterol) fumarate (as dihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Foradile. **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 Foradile.**

Where to find information in this leaflet:

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

1. Why am I using Foradile?

Foradile contains the active ingredient formoterol (eformoterol) fumarate. Foradile capsules for inhalation belong to a group of medicines called bronchodilators.

Foradile is 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.

2. What should I know before I use Foradile?

Warnings

Do not use Foradile if:

- you are allergic to formoterol (eformoterol) fumarate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
You may get a skin rash, difficulty in breathing, hay fever, swelling of the face, faintness or other symptoms if you use it.
- you are well controlled with an inhaled corticosteroid
- you only need short-acting beta-2-agonist medicines once in a while.
- the use by (expiry) date printed on the pack has passed
If you take this medicine after the expiry date has passed, it may not work as well as it should.
- the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

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 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.

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

Check with your doctor if you:

- have any other medical conditions, especially any of the following:
 - 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
- have any allergies to:
 - lactose (milk sugar)
 - any other medicines

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

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

Check with 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.

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

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

Asthma

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).

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 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.

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.**

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

4. How do I 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.**

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.

For chronic obstructive pulmonary disease (COPD)

Adults

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

When to use Foradile

- 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 Foradile

- **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 Foradile

Foradile should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember, and then go back to using it as you would normally.

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

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

If you use too much Foradile

If you think that you have used too much Foradile, 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.

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.

5. What should I know while using Foradile?

Things you should 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.**

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

Things you should 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.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Foradile affects you.

Foradile 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.

Looking after your medicine

- 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.

Follow the instructions in 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 young children cannot reach it.

When to discard your medicine

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

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 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
<ul style="list-style-type: none">trembling or shakinessmuscle aching or crampspalpitations (feeling that your heartbeat is unusually fast or irregular)headachedizzinessfeeling anxious, nervous or upsetbeing unable to sleepsore mouth or throat from inhaling the powder in the capsulechanged sense of tastenausea (feeling sick)dry mouth	<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
<ul style="list-style-type: none">an irregular heart beatexcessive 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 breathingsudden worsening of breathing problems after having a dose of Foradilemuscle 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	<p>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.</p>

itchy skin rash (hives); swelling of the face, lips, tongue, eyelids or other parts of the body.	
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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.

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.

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 Foradile contains

Active ingredient (main ingredient)	formoterol (eformoterol) fumarate dihydrate.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">Lactose monohydrate.GelatinOPACODE monogramming ink S-1-277002 BLACK.
Potential allergens	Lactose

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

What Foradile 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 (Aust R 58673).

Who distributes Foradile

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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