Formoterol fumarate dihydrate
12 microgram

Capsules for inhalation

Novartis

Foradil
Foradil® capsules for inhalation

Powder for inhalation
Intended for use with the inhaler provided in the pack.

Composition:
Each capsule contains:
Formoterol fumarate dihydrate 12 microgram.

Inactive Ingredients: see section 6 “Additional information”.

Read this leaflet carefully and in its entirety before using this medicine.
This leaflet contains summary information regarding the medicine. If you have further questions, contact the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.
1. WHAT IS THE MEDICINE INTENDED FOR?
For the treatment of reversible airway obstruction diseases, including asthma and exercise induced bronchospasm in patients receiving inhaled corticosteroids. Prophylaxis and treatment of airway constriction in patients with Chronic Obstructive Pulmonary Disease (COPD) including chronic bronchitis and emphysema. Foradil makes breathing easier by opening the small air passages of the lungs and helping them to remain relaxed and open for about 12 hours. If used according to your doctor’s instructions, Foradil should help keep you free of symptoms both during the day and night.

Therapeutic group: Bronchodilator, long-acting beta2 receptor agonist.

2. BEFORE USING THE MEDICINE
If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. The medicine contains lactose. Use of the preparation in children below 6 years of age is not recommended because of lack of clinical experience.
This medicine is usually not intended for infants and children below 6 years of age. The medicine can be used in elderly patients (aged 65 years or over) at the same dose as other adults.

**Do not use the medicine if:**
- you are breastfeeding.
- you are sensitive (allergic) to the active ingredient formoterol or to any of the other ingredients contained in the medicine, detailed in section 6. If this applies to you, tell the doctor without taking Foradil. If you think you may be allergic, ask your doctor for advice.
- you are well controlled with an inhaled corticosteroid.
- you only need short-acting beta2-agonist medicines (short-acting bronchodilators), occasionally.

**Special warnings regarding the use of the medicine:**
If you feel breathless or wheezy while under treatment with Foradil, you should continue to use it, but go to the doctor as soon as possible in case you need another medicine.
If you have asthma: do not use Foradil as the only asthma medicine. Use Foradil only with an inhaled corticosteroid.
When taking Foradil, other medicines that contain long-acting beta2-agonists, such as salmeterol, should not be used.

In some clinical studies with Foradil, serious asthma attacks have been observed.

Do not start Foradil or increase the dose recommended by your doctor while you are having an asthma attack.

Do not change or stop any of the medicines to control or treat your breathing problems, including inhaled corticosteroids. The doctor will adjust your medicines as needed.

If you have asthma, do not use Foradil to relieve sudden wheezing. Always have a short-acting beta2-agonist medicine (such as salbutamol inhaler) with you to treat sudden asthma symptoms.

Foradil belongs to a class of medicines called long-acting beta2-agonists (LABAs). A large study with a different LABA showed an increase in the risk of death due to asthma. No study has been done to know if this is also an effect of Foradil. Talk to your doctor about the risks and benefits of treating your asthma with Foradil.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or plan to become pregnant. Foradil should not be used during pregnancy unless the doctor advises you to do so. The doctor will tell you about the
risks of taking Foradil during pregnancy.
If you suffer from any heart disease, from an overactive thyroid, from diabetes, from high blood pressure, from epilepsy, from liver problems.
If you have severe lactose intolerance, as Foradil contains lactose (milk sugar).
If you are taking medicines belonging to the beta-blocker group (including eye drops).
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 a heart disorder, such as prolongation of QT interval (E.C.G. changes).
If you have pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure).

If you are taking other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:
monoamine oxidase inhibitors (MAO inhibitors) or tricyclic antidepressants, which are types of medicines used to treat depression and mood disturbances; 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; steroids, which are often used to treat
asthma and other inflammatory diseases; diuretics, which are used to treat edema (water retention), heart failure and high blood pressure; beta blockers, which are a class of medicines used to treat high blood pressure, heart failure, angina, anxiety, abnormal heart rhythm. Certain eye drops used to treat glaucoma 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 which control mental disorders such as schizophrenia, mania, psychotic conditions and anxiety; 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 airway diseases, such as theophylline or aminophylline; macrolide antibiotics (e.g. erythromycin; azithromycin); inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform the doctor that you use Foradil if you are to have a surgery under anaesthesia. Your doctor may change the dose or even stop one of the 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 medicines regularly. **DO NOT STOP** or reduce the dose even if you feel much better.
Pregnancy and breast feeding:
Do not use the medicine if you are breastfeeding. Consult the doctor before taking any medicine.
Consult the doctor before starting treatment if you are pregnant or plan to become pregnant. Foradil should not be used during pregnancy unless the doctor advises you to do so. The doctor will tell you about the risks of taking Foradil during pregnancy.

Driving and operating tools or machines:
Use of this medicine may cause dizziness in some patients. If you feel dizzy, do not drive a vehicle, use machines or perform any other task that requires your attention.

3. HOW TO USE THE MEDICINE?
Always use according to the doctor’s instructions. Check with the doctor or pharmacist if you are not sure.
Dosage is according to doctor’s instructions only. Do not exceed the recommended dosage.
The doctor will tell you how often to use Foradil and how much to take, depending on your needs. Do not change the dose without consulting the doctor. Carefully follow the doctor’s or pharmacist’s instructions, even if they differ from the
For asthma therapy, you will always be prescribed Foradil in addition to an inhaled corticosteroid.

The regular dose of Foradil for adults is 1 or 2 capsules twice a day. The maximum recommended dose per day for adults is 4 capsules. If your regular dose is 1 capsule twice a day, you may use 1 or 2 extra capsules during the day for relief of ordinary symptoms, but only if necessary. However, if 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. Always have a short-acting beta2-agonist medicine (such as salbutamol inhaler) with you to treat sudden asthma symptoms.

The recommended dose for children aged 6 years or older is 1 capsule twice a day. The maximum recommended dose per day for children is 2 capsules.

To prevent asthma attacks caused by exercise, use 1 capsule at least 15 minutes before exercise. This is the recommended dose for adults and for children aged 6 years or older. In some cases, if you are an adult, your doctor may advise you to use 2 capsules in order to prevent shortness of breath accompanied by wheezing or bronchospasm. If you are treated for regular asthma, the treatment will always include inhaled corticosteroids for the asthma treatment.

For chronic obstructive pulmonary diseases, the regular maintenance dose in adults
is 1 capsule twice a day.

**Do not swallow the capsules!** Use them only by inhalation of the capsule content with the enclosed inhaler.

Use the Foradil capsules **only with the inhaler** provided in the pack. This inhaler has been specially developed for use with Foradil capsules.

Remove the capsule from the blister pack just before use. Make sure your fingers are completely dry so that the capsule does not get wet.

**Do not swallow the capsule.** The powder in the capsule is to be used for inhalation only. See instructions for use below.

**Attention:**

Foradil is suitable for children aged 6 years or older who are able to handle the inhaler correctly. Children should only use the inhaler with the help of an adult.

1. The capsules may break when the blue buttons are pressed (step 5), and small fragments might get into your mouth or throat when you inhale. You can help to prevent this by:
   - Pressing the blue buttons only once.
   - Keeping the capsules in their original package (blister packs) before use.
   - Storing the capsules at a temperature not higher than 25°C.
• Protecting the capsules from moisture.
2. The capsule is made of edible gelatin, which is not harmful. Any fragments of gelatin that get into your mouth or throat can be swallowed.
3. If the capsule is jammed in the capsule chamber, open the inhaler, turn it upside down and gently tap on the bottom.
4. If the blue buttons get stuck, gently pull the blue buttons back into their initial position with the help of the “winglets”.
5. Signs that you have really taken the dose:
   • Hearing a whirring/buzzing noise when breathing in through the inhaler.
   • Sweet taste in the mouth, from the lactose. You may feel powder on the back of your throat. This is normal.
   • The capsule is empty.
6. In order to remove powder from the inside of the inhaler:
   • Use a dry tissue or a soft brush.
   • Remember that the inhaler must never be washed.

**Tests and follow-up:**
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.

Signs of an overdose include: nausea, vomiting, tremor, headache, dizziness (possible symptoms of high blood pressure), tachycardia or irregular heart rate, palpitations, drowsiness, hypokalaemia, hyperglycaemia.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to the nearest hospital emergency room and bring the package of the medicine with you.

This medicine is to be taken at specific time intervals, as determined by the attending doctor. If you forget to take this medicine at the specified time, take the dose as soon as you remember. If it is almost time for your next dose, do not use a double dose of Foradil to make up for the one that you missed; just go back to your regular dosing schedule.

Stick to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor. If you have additional questions about the use of the medicine, how Foradil works or why this medicine was prescribed for you, consult the doctor or pharmacist.
4. SIDE EFFECTS
Like with any medicine, using Foradil may lead to side effects in some of the users. Do not be alarmed following reading the list of side effects. You may experience none of them. **Refer to the doctor immediately if** you have one or more of the following effects:

Serious uncommon side effects (likely to affect between 1 and 10 of every 1,000 patients): Bronchospasm with wheezing or coughing and difficulty in breathing.

Serious very rare side effects (likely to affect fewer than 1 in every 10,000 patients): Allergic reaction, for example feeling faint (low blood pressure), rash, itching or swelling of the face.

Side effects with unknown frequency: Crushing chest pain (symptoms of angina pectoris); symptoms including muscle weakness, muscle spasms, or an abnormal heart rhythm (these symptoms could mean you have a low blood potassium level); irregular heart beat (including fast heart beat).

**Additional side effects:**
In some clinical studies with Foradil, serious asthma attacks (severe increase in shortness of breath, cough, wheezing or chest tightness which can result in hospitalization) have been observed.
Common side effects (likely to affect between 1 and 10 of every 100 patients): Headache; tremor; palpitations.

Uncommon side effects (likely to affect between 1 and 10 of every 1,000 patients): Agitation; anxiety; feeling nervous; difficulties with sleeping; dizziness; fast heart beat; throat irritation; dry mouth; muscle cramps; muscle pain.

Very rare side effects (likely to affect fewer than 1 of every 10,000 patients): Nausea; distorted sense of taste; swelling of hands, ankles or feet; excessive thirst, frequent urination and tiredness over an extended period of time (a possible indication of high blood sugar).

Additional reported side effects: Cough; rash; headache and dizziness (possible symptoms of high blood pressure).

If one or more of these side effects affect you severely, tell your doctor. Some of the side effects disappear as you get used to the medicine.

If a side effect gets worse, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.
Adverse reactions and drug interactions in children:
Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child!
See above for details of special side effects and drug interactions.

5. HOW TO STORE THE MEDICINE?
• Avoid poisoning! This medicine and all other medicines should be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
• Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
• Do not use this medicine after the expiry date (exp. date) stated on the package. The expiry date relates to the last day of that month.
Do not store above 25°C. Keep the capsules in the original package (blister packs) together with the inhaler. Protect from moisture.
When starting a new pack of Foradil, always discard the old inhaler and use the one provided in the new pack.
6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate (contains milk proteins). The capsule is made of edible gelatin.
Each capsule contains about 25 mg lactose.
Composition of the printing ink on the capsule:
Shellac, Iron oxide, black (CI 77499, E 172), Isopropyl alcohol, n-butyl alcohol, propylene glycol, water, purified, dehydrated ethanol, ammonium hydroxide 28%.

How does the medicine look and what is the content of the package:
White free flowing powder in a clear hard gelatin capsule, marked ‘CG’ on the cap and ‘FXF’ on the body or ‘CG’ on the body and ‘FXF’ on the cap in black ink, size 3.
30 or 60 capsules (not all pack sizes may be marketed).

Registration Holder: Novartis Israel Ltd.,
36 Shacham St., Petach-Tikva.

Manufacturer: Novartis Pharma Stein AG, Stein, Switzerland for Novartis Pharma AG, Basel, Switzerland.
This leaflet was checked and approved by the Ministry of Health in November 2013.

Registration number of the medicine as specified in the Registry of medicines at the Ministry of Health:
101 97 28552
The inhaler consists of the following parts:

1. A blue cap to protect the mouthpiece.
2. The inhaler base that allows the proper release of medicine from the capsule.
3. A mouthpiece.
4. A capsule chamber.
5. A blue button on each side.
6. An air inlet channel.

Instructions for use:

1. Pull off the cap (see picture no. 1).
2. Open the capsule chamber. Hold the inhaler base firmly and turn the mouthpiece in the direction of the arrow (see picture no. 2).
3. Make sure your fingers are completely dry. Remove one capsule from the blister pack just before use and place it flat on the bottom of the capsule chamber. IMPORTANT: Do not put the capsule into the mouthpiece! (see picture no. 3).
4. Close the capsule chamber by turning the mouthpiece back until you hear the "click" (see picture no. 4).
5. To release the powder from the capsule:
   - Hold the inhaler in the upright position with the mouthpiece upward.
   - Pierce the capsule by firmly pressing together both blue buttons at the same time. Then release the buttons. Do this only once.
1. 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.

2. Place the mouthpiece in your mouth and tilt your head slightly backward so that you can inhale your medicine deeply into your airways:

   - Breath out fully (See picture no. 6).
   - Breathe in rapidly but steadily and as deeply as you can (See picture no. 7).
   - To inhale your medicine deeply into your airways:
     - Place the mouthpiece in your mouth and tilt your head slightly backward.
     - Inhale quickly and steadily as deeply as possible.

3. Note: You should hear a whirring noise as the capsule spins around in the space above the capsule chamber.

4. If you do not hear this noise, open the capsule by pressing the buttons repeatedly. Then repeat step 7.

5. After you have used up all the powder, open the capsule and use a dry tissue or a soft brush to remove any powder left inside.

6. After breathing in through the inhaler, hold your breath for as long as you comfortably can while the capsule spins around in the space above the capsule chamber. If there is, repeat steps 6 to 8.

7. After using the inhaler, hold your breath for as long as you comfortably can while the capsule spins around in the space above the capsule chamber.

8. After breathing in through the inhaler, hold your breath for as long as you comfortably can while the capsule spins around in the space above the capsule chamber. If there is, repeat steps 6 to 8.

9. After you have used up all the powder, open the capsule and use a dry tissue or a soft brush to remove any powder left inside.

10. Close the mouthpiece and replace the inhaler (See picture no. 8).

Note: DO NOT USE WATER to clean the inhaler.