

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Foradil® capsules for inhalation 12 mcg

Powder for inhalation

Active ingredient:

Each capsule contains:

Formoterol fumarate dihydrate 12 microgram

Inactive and allergenic ingredients appear in section 6 – “Additional Information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of asthma (including nocturnal asthma and symptoms caused by exertion) in patients being treated with inhaled corticosteroids, who require in addition long-acting beta-2 receptor agonist medicines, in accordance with current treatment guidelines. For treatment and prophylaxis of airway constriction in patients with Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema.

Therapeutic group:

Beta-2 receptor agonist.

Medicines from this family make breathing easier by relaxing contracted muscles in the air passages of the lungs.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient formoterol fumarate dihydrate, or to any of the additional ingredients contained in the medicine (see section 6 in the leaflet).

Special warning regarding use of the medicine

Before treatment with Foradil, tell the doctor if:

- You are taking any another medicine to treat asthma
- You are suffering from any heart problem
- You have high blood pressure
- You have an overactive thyroid gland
- You have an aneurysm (swollen area in an artery because the wall of the artery is weak)
- You have a heart disorder such as abnormal electrical signal called “prolongation of QT interval”
- You have diabetes
- You have pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure)

Other special warnings

- Do not use Foradil to treat a sudden asthma attack. Your doctor will prescribe another inhaler for you for this.
- It is very important to keep using your other medicines for treatment of asthma (inhaled steroids known as preventer medicines) regularly. **Do not stop** using them or change the dosage when you start using Foradil.
- If you feel breathless or if you have wheezing while under treatment with Foradil, you should continue to use the medicine, but refer to the doctor as soon as possible in case you need another medicine.
- 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 high sugar levels in the blood. Therefore, you might need to monitor your blood sugar levels if you are diabetic.

Children and adolescents:

This medicine is not intended for children under the age of 6, as the safety and efficacy of its use have not been established in this age group.

Drug interactions:

If you are taking, have recently taken or may take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Particularly if you are taking:

- Medicines for the heart, including irregular heartbeat, angina and heart failure
- Medicines for high blood pressure
- Beta blockers (either as tablets or as eye drops)
- Diuretics
- Medicines to treat depression, for example, monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants
- Anti-histamines or cold medicines
- Steroids (your doctor will know which medicines these are)
- Sympathomimetic medicines, which are adrenaline-like medicines used to treat asthma and nasal congestion
- Phenothiazine derivatives, which are a group of medicines used to control mental disorders such as schizophrenia, mania, psychotic conditions and anxiety
- Xanthine derivatives, which are a class of medicines used to treat asthma and chronic obstructive airways diseases, such as theophylline or aminophylline
- Macrolides (for example, erythromycin), used to treat bacterial infections
- Anesthetics like halogenated hydrocarbons (halothane), used during surgeries
- Anticholinergic medicines (for example, ipratropium bromide) used to treat gastrointestinal or genital disorders.

Pregnancy, breast-feeding and fertility:

If you are pregnant, breast-feeding, think you may be pregnant or are planning a pregnancy, consult with your doctor or pharmacist before taking the medicine.

Driving and using machines:

Use of this medicine can cause dizziness in some patients. If you feel dizzy, do not drive or operate machinery.

Important information about some of the ingredients of the medicine:

If you have been told by your doctor that you have an intolerance to some sugars, refer to the doctor before using the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure regarding the dosage and treatment regimen of the preparation.

The doctor will tell you how often to use Foradil and how much to take, according to your needs. Do not change the dosage without consulting with the doctor.

Carefully follow the doctor or pharmacist's instructions, even if they differ from the information contained in this leaflet.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is:

Asthma treatment

For the treatment of asthma, you will always be prescribed Foradil in addition to an inhaled corticosteroid.

Adults

The regular dosage of Foradil **for adults** is 1 or 2 capsules, twice a day.

The maximum recommended dosage for adults is 4 capsules per day.

If your regular dosage 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 two days a week, you should refer to your doctor as soon as possible because it may be that your condition is getting worse.

Always have a short-acting beta 2-agonist medicine (such as salbutamol inhaler) with you, to treat sudden asthma symptoms.

Children

The recommended dosage **for children** aged 6 or older is 1 capsule twice a day.

The maximum recommended dosage for children is 2 capsules per day.

For the treatment and prevention of airway obstruction in patients with chronic obstructive pulmonary disease

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

If you are being treated for regular asthma, the treatment will always include inhaled corticosteroids for the asthma treatment.

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

Do not exceed the recommended dose.

- Do not stop or reduce the dosage 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 take these medicines regularly.
- Do not increase your dosage of Foradil without talking to your doctor first.
- If you feel nauseated or very shaky or if you have an unusually fast heart rate, your Foradil dosage may be too high. Tell your doctor as soon as possible.

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

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

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

Do not swallow the capsule.

Do not open and disperse the content of the capsule. The powder in the capsules is intended for inhalation using the inhaler only.

See instructions for use below.

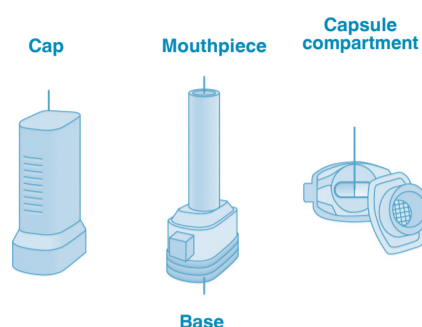
Attention:

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

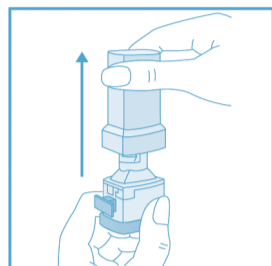
- The capsule may break when the blue buttons are pressed (step 5), and small fragments might get into your mouth or throat when you inhale. You can help prevent this situation by:
 - Pressing the blue buttons only once.
 - Keeping the capsules in their original package (tray package) before use.
 - Storing the capsules at a temperature not exceeding 25°C.
 - Protecting the capsules from moisture.
- 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.
- If the capsule is jammed in the capsule chamber, open the inhaler, turn it upside down and gently tap on the bottom.
- If the blue buttons are stuck, gently pull the blue buttons back into their initial position with the help of their “winglets”.
- Signs that you have really taken the dose:
 - Hearing a whirring/buzzing sound 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 situation is normal.
 - The capsule is empty.
- 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.

Instruction on how to use the capsules with the inhaler

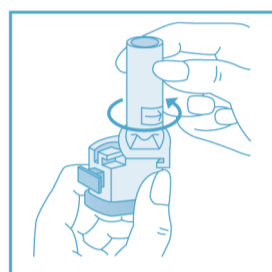
A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.



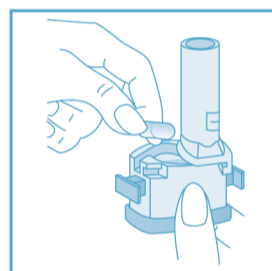
1. Pull off the cap.



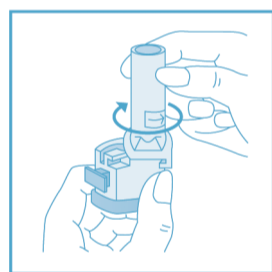
2. To open the inhaler, hold the inhaler firmly and turn the bottom of the mouthpiece in the direction of the arrow (the below arrow on the bottom of the mouthpiece).



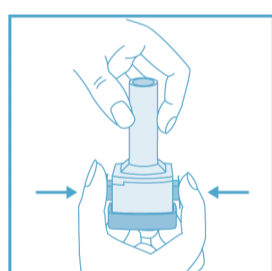
3. Take one of the capsules out of the tray package and place it in the bottom of the capsule compartment. It is important that you remove the capsule from the tray package **only** immediately before use.



4. Close the capsule compartment by twisting the mouthpiece back until you hear a 'click'.



5. To release the powder from the capsule:
 - Keep the inhaler upright with the mouthpiece facing upwards.
 - Pierce the capsule by firmly squeezing the two blue buttons at the same time. Then, release the buttons. Perform this step **once only**.
 - Although the capsule is now pierced, the powder will not be released until you inhale it.



6. Breathe out fully.



7. Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs. You should hear the sound of the capsule spinning in the inhaler. If you do not hear this sound, the capsule may be stuck in the capsule compartment. If this occurs, open the inhaler and try to loosen the capsule to release it from the capsule compartment. **Do not** try to loosen the capsule by repeatedly pressing the buttons.



8. If you have heard the whirring sound, **hold your breath** for as long as you can while taking the inhaler out of your mouth. Then, breathe normally. Open the capsule compartment to check if any powder is still in the capsule. If powder remains in the capsule, repeat steps 6 to 8.
9. After use, remove the empty capsule and close the mouthpiece.
10. Replace the cap of the inhaler.
11. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush.

Very occasionally, very small pieces of the capsule can get into your mouth. If this happens, you may be able to feel the pieces on your tongue. The capsule is made of gelatin, which is harmless to humans, and will soften or dissolve in the mouth and be swallowed. The chances of this happening will be increased if the capsule is pierced several times (step 5); hence, it is recommended that you pierce each capsule only once.

If you forget to take the medicine

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

If you have taken a higher dosage

If you, or anyone else, accidentally takes too large a dose, refer immediately to the doctor or proceed to the nearest hospital emergency room and bring the package of the medicine with you.

If you stop taking the medicine

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting 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. If you have further questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Foradil may lead to cause effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Certain side effects may be serious

Stop using the medicine and refer to the doctor immediately if you notice:

- Bronchospasm with wheezing or coughing and difficulty in breathing (uncommon side effects, occurring in 1-10 in 1,000 users).
- An allergic reaction, such as feeling faint (you might have low blood pressure), rash, itching or facial swelling (rare side effects, occurring in 1-10 in 10,000 users).
- Muscle weakness, muscle spasms or an abnormal heart rhythm (these could mean you have a low blood potassium level) (rare side effects, occurring in 1-10 in 10,000 users).
- Irregular or rapid heartbeat (rare side effects, occurring in 1-10 in 10,000 users).
- Crushing chest pain (signs of angina pectoris) (very rare side effect, occurring in less than one user in 10,000).

Additional side effects:

Common side effects (effects that occur in 1-10 in 100 users): headache, tremor, palpitations.

Uncommon side effects (effects that occur in 1-10 in 1,000 users): Agitation, anxiety, nervousness, sleeping difficulties, dizziness, fast heartbeat, throat irritation, dry mouth, muscle cramps, muscle pain, worsening of asthma.

Rare side effects (effects that occur in 1-10 in 10,000 users): Nausea.

Very rare side effects (effects that occur in less than one user in 10,000): distorted sense of taste, swelling of hands, ankles or feet, changes in blood pressure, excessive thirst, frequent urination and tiredness over an extended period (may indicate high blood sugar levels).

Side effects of unknown frequency (effects whose frequency has not yet been determined): Headache and dizziness (symptoms of high blood pressure), cough and rash.

Some of the side effects disappear after a period of adjustment to the medicine.

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

The doctor may switch you to another medicine.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Do not store above 25°C.
- Store in the original package (protect from moisture).
- Do not dispose of the medicine in the household waste or through the sewers. Ask your pharmacist how to dispose of medicines that are no longer in use. These measures are required to protect the environment

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains: Gelatin and black ink (containing shellac, black iron oxide (CI 77499, E 172), isopropyl alcohol, N-butyl alcohol, propylene glycol, purified water, dehydrated ethanol and ammonium hydroxide 28%), lactose.

What does the medicine look like and what are the contents of the package:

White powder in a clear gelatin capsule, marked 'GC' on the capsule cap and 'FXF' on the capsule body or 'GC' on the capsule body and 'FXF' on the capsule cap in black ink.

The package contains 30 or 60 capsules (not all package sizes may be marketed).

Registration Holder and Importer: Novartis Israel Ltd., P.O.B. 7126, Tel Aviv.

Revised in July 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

101 97 28552