

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Foradil Capsules For Inhalation

12 micrograms

Powder for inhalation

Active ingredient

Each capsule contains 12 mcg formoterol fumarate dihydrate.

Inactive ingredients and allergens in this medicine: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 to yours.

1. What is this medicine intended for?

To treat asthma (including nocturnal asthma and exercise-induced symptoms) in patients treated with inhaled corticosteroids who also require a long-acting beta 2 receptor agonist in accordance with current treatment guidelines.

To treat and prevent constriction of airways in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

Therapeutic group:

beta 2 receptor agonist.

Medicines from this group make breathing easier by relaxing muscle spasms in the air passages of the lungs.

2. Before using this medicine

Do not use this medicine if:

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

Special warnings about using this medicine

Before using Foradil, tell your doctor if:

- you are taking any other asthma medicine
- you suffer 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 an abnormal electrical signal called "prolongation of QT interval"
- you are diabetic
- you have pheochromocytoma (a tumour of the adrenal gland that can affect blood pressure)

Additional special warnings

- Do not use Foradil to treat a sudden asthma attack. Your doctor will prescribe another inhaler for this.
- It is very important to keep using your other asthma medicines (inhaled steroids known as preventer medicines) regularly. **DO NOT** stop using them or change the dose when you start using Foradil.
- If you feel that you are getting breathless or wheezy while you are using Foradil, you should continue to use it, but contact your doctor as soon as possible in case you need a different 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 increased 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 6 years of age, because its safety and effectiveness has not been proved in this age group.

Interactions with other medicines

If you are taking, have recently taken or might take any other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines for your heart including irregular heartbeat, angina, and heart failure
- medicines for high blood pressure
- beta blockers (either as tablets or eye drops)
- water tablets (diuretics)
- medicines for depression, for example, monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants
- anti-histamines or cold remedies
- medicines called steroids (your doctor will know which these are)
- sympathomimetic agents, 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, for example theophylline or aminophylline, which are a class of medicines used to treat asthma and chronic obstructive airways diseases
- macrolide antibiotics (for example erythromycin) used to treat bacterial infections
- anaesthetics like halogenated hydrocarbons (for example halothane), which are used during surgery
- anticholinergic medicines (for example ipratropium bromide) used to treat gastrointestinal disorders and genital or urinary disorders.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

In some patients, using this medicine can cause dizziness. If you feel dizzy, do not drive or operate machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Your doctor will tell you how often to use Foradil and how much to take, according to your needs.

Do not change your dosage without consulting your doctor.

Follow your doctor's or pharmacist's instructions precisely, even if they are different from the information in this leaflet.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

For the treatment of asthma

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

Adults

The usual **adult** dose is one or two capsules, twice a day. one capsule = one puff.

The maximum recommended dose for adults is four capsules a day. If your usual dosage is one capsule twice a day, you may use one or two additional capsules during the day to relieve normal symptoms, **but only if you need it.**

However, if you need to use additional capsules for more than two days a week, contact your doctor as soon as possible, because your condition could be getting worse.

Make sure to always carry a short-acting beta 2 receptor agonist (such as a salbutamol inhaler) to treat sudden symptoms of asthma.

Children

The usual dose in **children** aged over 6 years is one capsule twice a day.

The maximum recommended dose for children is two capsules a day.

For the treatment and prevention of constriction of the airways in patients with COPD

To prevent asthma attacks caused by physical activity, use one capsule at least 15 minutes before your physical activity. This is the recommended dose for adults and children over 6 years of age. In some cases, if you are an adult, your doctor may advise you to take two capsules to prevent shortness of breath with wheezing or bronchospasm.

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

For COPD, the usual maintenance dose for adults is one capsule twice a day.

Do not exceed the recommended dose.

- Do not stop or reduce the dose 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 use these medicines regularly.
- Do not increase your dose of Foradil without discussing this with your doctor first.
- If you feel nauseous or very unstable (shaky) or if you have an unusually fast heart beat, your Foradil dose may be too high. Tell your doctor as soon as possible.

Do not swallow the capsules! Foradil capsules must only be used with the inhaler provided. Do not put other types of capsules in the inhaler.

Use Foradil capsules **only with the inhaler** provided in this pack. This inhaler was developed specifically for use with Foradil capsules. Only remove the capsule from the blister pack **immediately before** you use it. Make sure your fingers are completely dry, so that the capsule does not get wet.

Do not open the capsule and release its content.

See Instructions for Use below.

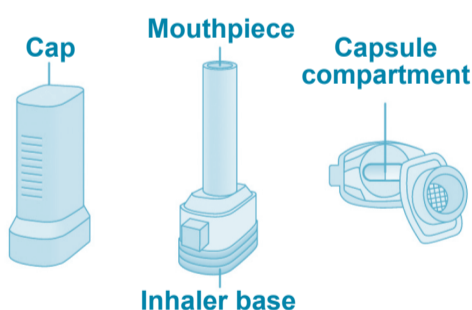
Note:

Foradil is suitable for children over 6 years of age who are able to use the inhaler correctly. Children may only use the inhaler with the help of an adult.

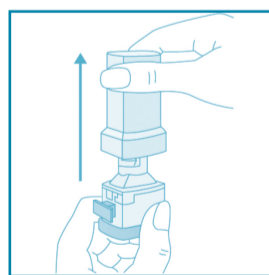
1. The capsule may fragment when the blue buttons are pressed (Step 5 in the Instructions for Use below), and small pieces may reach the mouth or throat when inhaling. You can prevent this by:
 - pressing the blue buttons only once.
 - keeping the capsules in their original package (blister strip) until used.
 - storing the capsules at a temperature up to 25°C.
 - protecting the capsules from moisture.
2. The capsule is made of harmless, edible gelatine. Any pieces of gelatine reaching your mouth or throat can be swallowed.
3. If the capsule sticks in the capsule chamber, open the inhaler, turn it upside down and tap the base gently.
4. If the blue buttons get jammed, gently prise them out to their original position using the button flanges.
5. Signs that you have actually taken the dose:
 - You hear a whirring/buzzing sound when inhaling through the inhaler.
 - You feel a sweet taste in your mouth, from the lactose. You may feel powder in the back of your throat; this is normal.
 - The capsule is empty.
6. To remove powder from the inside of the inhaler:
 - Use a dry cloth or a soft brush.
 - Remember to never rinse the inhaler.

How to use the capsules with the inhaler device

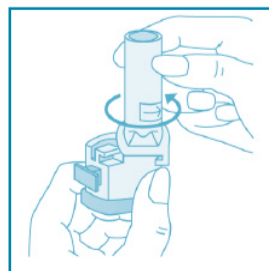
A child should be shown how to use the inhaler correctly and should only use it with the help of an adult.



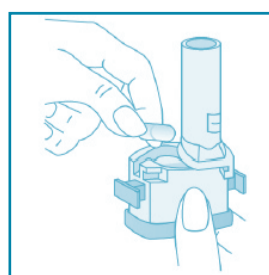
1. Pull off the cap.



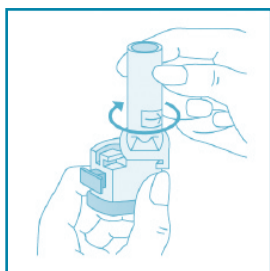
2. To open the inhaler, hold the inhaler firmly and turn the bottom of the mouthpiece in the direction of the arrow (the arrow on the bottom of the mouthpiece).



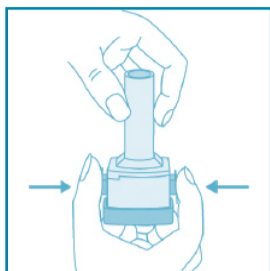
3. Take one capsule out of the blister strip and place it in the bottom of the capsule compartment. It is important that you remove the capsule from the blister strip **only** immediately before use.



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



5. To release the powder from the capsule:
- Hold the inhaler upright with the mouthpiece pointing up.
 - Pierce the capsule by firmly squeezing the two blue buttons at the same time. Next, release the buttons. Do this **only once**.
 - 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 capsule spinning in the inhaler. If you do not hear this sound, the capsule may be stuck in the compartment. If this occurs, open the inhaler and try to loosen the capsule by prising it out of 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 see if any powder is still in the capsule. If powder remains in the capsule, repeat steps 6 to 8.
9. After use, tip out the empty capsule and close the mouthpiece.
10. Replace the inhaler cap.
11. If you need to clean the inhaler, wipe the mouthpiece and capsule compartment with a dry cloth or a clean soft brush.

Often, very small pieces of the capsule can get in your mouth. If this happens, you may be able to feel these pieces on your tongue. The capsule is made of gelatine 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 this medicine

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

If you have accidentally taken a higher dose

If you, or anyone else, accidentally takes too much, immediately see your doctor or go to the nearest hospital emergency room and bring the medicine package with you to show what medicine you took.

If you stop taking this medicine

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Foradil may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Some side effects can be serious

Stop using this medicine and contact your doctor straight away if you notice:

- bronchospasm with wheezing or with coughing and difficulty in breathing (uncommon side effect, affects up to 1 in 100 users).
- an allergic reaction such as feeling faint (you might have low blood pressure), a rash, itching or facial swelling (rare side effect, affects up to 1 in 1,000 users).
- muscle weakness, muscle spasms, or an abnormal heart rhythm (these could mean you have a low blood potassium level) (rare side effects, affect up to 1 in 1,000 people).
- irregular or fast heart rate (rare side effect, affects up to 1 in 1,000 users).
- a crushing chest pain (symptoms of angina pectoris) (very rare side effect, affects less than 1 in 10,000 users).

Additional side effects

Common side effects (affect up to 1 in 10 users): headache, tremor, palpitations.

Uncommon side effects (affect up to 1 in 100 users): agitation, anxiety, feeling nervous, difficulties with sleeping, dizziness, fast heartbeat, throat irritation, dry mouth, muscle cramps, muscle pain, worsening of asthma.

Rare side effects (affect up to 1 in 1,000 people): nausea.

Very rare side effects (affect less than 1 in 10,000 users): distorted sense of taste, swelling of hands, ankles or feet, variations in blood pressure, excessive thirst, frequent urination, and tiredness over an extended period of time (may indicate high blood sugar levels).

Side effects of unknown frequency (the frequency of these effects has not been established yet): headache and dizziness (symptoms of high blood pressure), cough and rash.

Some of these side effects wear off once you get used to the medicine.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor. Your doctor may want to give you a different medicine.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated 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 packaging (protect from moisture).
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains: gelatine 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 monohydrate.

What the medicine looks like and contents of the pack:

white powder in a clear gelatine capsule marked 'CG' on the capsule cap and 'FXF' on the capsule body, or 'CG' on the capsule body and 'FXF' on the capsule cap in black ink. The pack contains 60 capsules.

License holder and importer's name and address: Sandoz Pharmaceuticals Israel Ltd., P.O. Box 9015, Tel Aviv, Israel.

Revised in June 2024.

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

101 97 28552