

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **FORADIL**[®]

formoterol fumarate dry powder capsules for inhalation

Read this carefully before you start taking **FORADIL**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FORADIL**.

Serious Warnings and Precautions

SERIOUS WARNING FOR ASTHMA PATIENTS TAKING FORADIL:

FORADIL increases the risk of asthma-related death. It may increase the risk of asthma-related hospitalizations in pediatric and adolescent patients. Therefore,

- FORADIL must **only** be used as an **add-on** therapy when your inhaled corticosteroid does not adequately control your asthma symptoms
- FORADIL must be used together with an inhaled corticosteroid
- The dose of FORADIL may be reduced (from two capsules twice daily to one capsule twice daily) or discontinued by your physician when your asthma is assessed as adequately under control.
- It is extremely important to make sure that children 6 to 18 years of age take both FORADIL and an inhaled corticosteroid. If this can not be guaranteed, speak to the prescribing physician as a combination product may be required.

For any concerns regarding the use of FORADIL, consult with your physician.

What is FORADIL used for?

Asthma (patient 6 years old and older):

FORADIL is used only as add-on therapy to an inhaled corticosteroid when an inhaled corticosteroid cannot control the asthma by itself.

FORADIL is a long-acting beta₂-agonist and **should not be used to provide relief for a sudden attack of breathlessness.**

Chronic Obstructive Pulmonary Disease (COPD):

FORADIL is used for the management of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema in adults.

How does FORADIL work?

- **FORADIL** belongs to a drug class known as a long-acting bronchodilator.

- FORADIL opens air ways in the lungs to make breathing easier, and keep them open and relaxed for about 12 hours.
- FORADIL must be used with an inhaled corticosteroid to reduce the inflammation of the lungs due to asthma.

What are the ingredients in FORADIL?

Medicinal ingredients: formoterol fumarate.

Non-medicinal ingredients: gelatin, lactose monohydrate, shellac glaze 45%, black iron oxide, isopropyl alcohol, n-butyl alcohol, propylene glycole, purified water , dehydrated ethanol, ammonium hydroxide 28%

FORADIL comes in the following dosage forms:

FORADIL comes as gelatin capsules containing a dry powder. The dry powder is INHALED into the lungs using the inhaler provided. FORADIL comes in blister packs containing 60 capsules. Each capsule of FORADIL contains 12 micrograms of *formoterol fumarate*

Do not use FORADIL if:

- You are not being treated with an inhaled corticosteroid (ICS) for your asthma. The ICS decreases the inflammation in your lungs while FORADIL opens the airways. Do not take FORADIL without an ICS
- you have heart problems
- you are allergic to formoterol fumarate or any of the nonmedicinal ingredients in FORADIL
- you are allergic to lactose (milk sugar)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FORADIL. Talk about any health conditions or problems you may have, including if:

- You have significantly worsening asthma
- You have health problems now or have had health problems in the past, especially heart disease, diabetes, overactive thyroid.
- If you have an aneurysm (area where an artery is swollen like a sack because the wall of the artery is weak).
- You have a heart disorder, such as rapid or irregular heart beat or an abnormal electrical signal called “prolongation of the QT interval”.
- You have high blood pressure.
- If you have pheochromocytoma (a tumor of the adrenal gland that can affect blood pressure)
- You are pregnant, plan to become pregnant or are breast-feeding

Other warnings you should know about:

Driving and Operating Machinery: Do not drive or operate machinery if you experience dizziness while taking FORADIL

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FORADIL:

- Short-Acting beta-agonists
- Medications used to treat depression or sad mood (monoamine oxidase inhibitors and tricyclic antidepressants)
- Antihistamines
- Water pills (diuretics)
- Beta-blockers for high blood pressure and certain eye drops for the treatment of glaucoma
- Steroids such as corticosteroids
- Drugs containing quinidine, disopyramide, procainamide, phenothiazine or xanthine derivatives (theophylline or aminophylline)
- Macrolide antibiotics (e.g. erythromycin; azithromycin; clarithromycin)
- Inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform your doctor that you use FORADIL if you are to have surgery under anaesthesia.

How to take FORADIL Aerolizer:

- It is very important that you take FORADIL exactly as your doctor tells you.
- Inhale the contents of the capsules using the Aerolizer inhaler. Do not swallow the capsules.
- Children 6 years of age or older should only use FORADIL if they are able to handle the inhaler correctly. They should only use the inhaler with the help of an adult.
- If the relief of your asthma is not as good as usual or does not last as long as usual, tell your doctor right away. A change from "usual" includes more wheezing, coughing, tightness or shortness of breath. More frequent severe asthma symptoms can occur in children 6-12 years old. Monitor your child's use of all asthma related medications and their response to FORADIL carefully.
- If your symptoms are waking you up at night tell your doctor right away. Your doctor may adjust your treatment.
- You may need emergency treatment if your asthma symptoms are not relieved, despite taking all your prescribed medications, and after resting for an hour.
- You should not use FORADIL to treat sudden asthma attacks. A short-acting bronchodilator (also known as a quick reliever e.g. salbutamol) should also be used when you have a sudden attack of shortness of breath, tightness, coughing and wheezing.
- If you are using more of your short-acting bronchodilating medication or if you feel that it is less effective tell your doctor right away. Your doctor may adjust your treatment.

You must continue to regularly take the anti-inflammatory medications (e.g., inhaled steroids) your doctor has prescribed. 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.

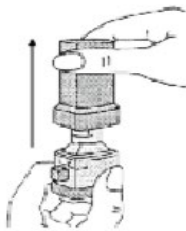
Your anti-inflammatory medications and FORADIL are designed to act together to best treat your asthmatic condition. Even though you feel better, do not stop or reduce your doses of FORADIL or your anti-inflammatory medications.

For children 6-18 years of age, treatment with a combination product containing an inhaled corticosteroid and long-acting bronchodilator is recommended, except in case where a separate inhaled corticosteroid and long-acting bronchodilator are required.

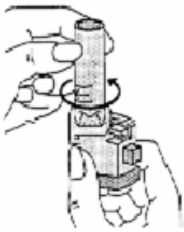
FORADIL should not be used with another long-acting bronchodilator alone (e.g. Oxeze or Serevent) or in combination with a steroid (e.g., Symbicort, Advair).

How do I use the FORADIL inhaler and capsules?

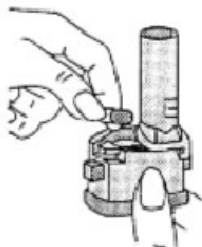
1. Pull off cap



2. To open, hold base of the inhaler firmly and turn the mouthpiece in the direction of the arrow.



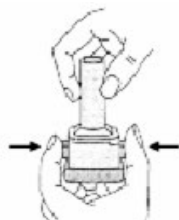
3. Remove the capsule from the blister pack. It is important to keep the capsule in the blister pack until you are ready to use it. Place the capsule in the capsule shaped compartment in the base of the inhaler.



4. Return the mouthpiece to the closed position.



5. Keeping the inhaler upright, firmly squeeze the two blue buttons fully **only once**. This will pierce the capsule. Release the buttons. Although the capsule is now pierced, the powder will not be released until you inhale it.



Please note that the capsule might splinter at this step and small fragments of gelatin might reach your mouth and throat. This gelatin is edible and is therefore not harmful. You can minimize the tendency of the capsule splintering by:

- *piercing the capsule only once*
- *keeping the capsules stored in a dry place at room temperature*
- *keeping the capsule in the blister pack until you are ready to use it.*

6. Breathe out fully.



7. Place the mouthpiece in your mouth and tilt your head slightly backward. Close your lips around the mouthpiece and breathe in steadily as deeply as you can. As you breathe in, you will inhale the medication into your lungs.



*You should hear a whirring noise as you breathe in because inhalation causes the capsule to spin around in the inhaler. **Please note** if you do not hear the whirring noise, the capsule may be stuck in the capsule-shaped compartment. If this occurs, re-open the inhaler carefully and pry the capsule out. You cannot loosen the capsule by repeatedly pressing the buttons.*

8. If you have heard the whirring noise, **hold your breath** for as long as you comfortably can while removing the inhaler from your mouth. Then breathe out.

9. After use, open the inhaler. Check that the capsule is empty. If it is not close the inhaler and re-inhale following steps 6, 7 and 8. Remove the empty capsule. Close the mouthpiece. Replace the cap.

How to clean the inhaler:

To remove any powder residues, wipe the mouthpiece and capsule compartment with a **dry** cloth or a small, soft, clean brush.

Usual dose:

ASTHMA:

You or your child will always be prescribed FORADIL in addition to an inhaled corticosteroid.

Adults: The regular dose of FORADIL for adults, is 1 or 2 capsules twice a day, once in the morning and again in the evening.

You should not use more than 2 capsules twice daily.

The dose of FORADIL may be reduced (from two capsules twice daily to one capsule twice daily) or discontinued by your physician when your asthma is assessed as adequately under control.

Children: The recommended dose for **children** 6 years of age or older is 1 capsule twice a day. The severity of asthma changes with age. Your child should therefore be periodically re-examined by a physician.

Your child should not use more than 1 capsule twice daily.

It is extremely important to make sure that children 6 to 18 years of age take both FORADIL and an inhaled corticosteroid. If this can not be guaranteed, speak to the prescribing physician as a combination product may be required.

COPD: The regular dose for adults, including elderly patients, is 1 or 2 capsules twice a day, once in the morning and again in the evening. You should not use more than 2 capsules twice daily.

FORADIL should not be taken more than twice daily.

Overdose:

If you develop nausea and/or vomiting, shakiness, headache, dizziness (possible symptoms of high blood pressure), fast or irregular heartbeat, or sleepiness, your dose of FORADIL may be too high. Seek immediate medical attention.

If you think you, or a person you are caring for, have taken too much FORADIL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

FORADIL should not be used more often than twice a day. If you forget to take a dose, take it as soon as possible. However, if it is almost time for your next dose, do not take the missed one, just go back to your regular dosing schedule. Never take a double dose.

What are possible side effects from using FORADIL?

These are not all the possible side effects you may feel when taking FORADIL. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- tremor,
- headache,
- dry mouth, or irritation of the mouth or throat.
- muscle cramps and pain,
- agitation, feeling nervous or tired,
- difficulty sleeping.

You should keep track of any side effects and if they persist, notify your doctor on your next visit.

FORADIL can cause abnormal blood test results. Your doctor will decide when to preform blood tests and will interpret the results.

If you feel you are getting breathless or wheezy while you are using FORADIL, you should continue to use it, but see your doctor as soon as possible in case you need another medicine. If this occurs immediately after a dose, stop taking the drug and seek immediate emergency medical attention.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Bronchospasm with wheezing or coughing and difficulty in breathing, immediately after taking your dose			X
Serious Asthma Attacks: severe			X

increase in shortness of breath, cough, wheezing, or chest tightness which can result in hospitalization			
RARE			
Decreased level of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		X	
VERY RARE			
Fast and irregular heartbeat			X
Angina Pectoris: Crushing pain in chest			X
Allergic Reaction: fainting, due to low blood pressure, rash, or itching, or swelling of the face, mouth or throat			X
High Blood Pressure: headache and dizziness			X
Increased Blood Sugar: frequent urination, thirst, and hunger		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep this medication at room temperature, in a dry place. Your car or the bathroom are not good choices.

The capsules should be removed from the blister pack just before use. Keep this medicine out of the reach of children because it may harm them. Do not use FORADIL after the expiry date marked on the carton.

If you want more information about FORADIL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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