

## CONSUMER INFORMATION

<sup>Pr</sup>Foradil\*

### formoterol fumarate dry powder capsules for inhalation

This leaflet is part III of a three-part "Product Monograph" published when FORADIL\* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FORADIL\*. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

What FORADIL\* is 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 is not adequate to control the asthma by itself.**

FORADIL\* is a long-acting beta<sub>2</sub>-agonist and **should not be used to provide relief for a sudden attack of breathlessness.**

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.

**Chronic Obstructive Pulmonary Disease (COPD):**

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

#### What it does?

- 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.

#### When it should not be used:

- If you are being treated for asthma, you should always be given both FORADIL\* and an inhaled corticosteroid (ICS) to use together. The ICS decreases the inflammation in your lungs while FORADIL\* opens the airways. Do not take FORADIL\* without an ICS. A third drug, a relief medication (e.g. salbutamol), should be used for any sudden attacks of breathlessness (asthma attacks).
- If you are allergic to formoterol fumarate or any of the nonmedicinal ingredients in FORADIL\*
- If you have heart problems
- If you have been told you are allergic to lactose (milk sugar)

#### What the medicinal ingredient is:

*formoterol fumarate.*

#### What the nonmedicinal ingredients are:

gelatin, lactose monohydrate

#### What dosage form it comes in:

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*

#### 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.

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

Before you use FORADIL\* talk to your doctor or pharmacist if:

- 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 taking certain medications, including ones you can buy without a prescription (see **INTERACTIONS WITH THIS MEDICATION**)
- You are pregnant, plan to become pregnant or are breast-feeding

**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.

Children 6 years of age or older should only use FORADIL\* if they are able to handle the inhaler correctly, (see "Proper use of

this medication”). They should only use the inhaler with the help of an adult.

**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).

**Important Notes:**

- It is very important that you take FORADIL\* exactly as your doctor tells you.
- 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 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.
- 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.

*Nothing in this material should stop you from calling your doctor or pharmacist with any questions or concerns you may have about using FORADIL\*.*

**INTERACTIONS WITH THIS MEDICATION**

As with other medicines, interactions with other drugs are possible. Therefore, do not take any other medicines unless you have discussed the matter with your physician or your pharmacist.

**Drugs that may interact with FORADIL\* include:**

- 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
- 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.

**Other Drugs:** Drugs such as quinidine, disopyramide, procainamide, phenothiazines, antihistamines, and tricyclic antidepressants may be associated with QT-interval prolongation and an increased risk of ventricular arrhythmia (see WARNINGS).

**PROPER USE OF THIS MEDICATION**

**How to take FORADIL\* Aerolizer\***

- Always use FORADIL\* Aerolizer\* exactly as your doctor or pharmacist has told you.
- **Inhale the contents of the capsules using the Aerolizer\* inhaler.** Do not swallow the capsules.
- Do not exceed the recommended 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. It is important to make sure that your child also understands and properly follows the asthma therapies prescribed to him/her. These will include in addition to FORADIL\*, a drug which reduces the inflammation in the lung due to asthma (also known as a preventive medication) and a short-acting bronchodilator (also known as a quick reliever)

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.** If you have difficulty breathing, tightness, wheezing or coughing and need relief, use the short-acting bronchodilator medication your doctor has prescribed for that purpose.

**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.

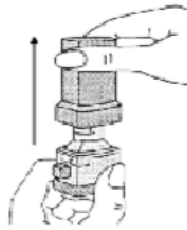
**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

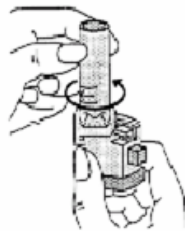
If you develop nausea and/or vomiting, shakiness, headache, dizziness (possible symptoms of high blood pressure), fast or irregular heartbeat, or sleepiness, your dose of FORADIL\* may be too high. Seek immediate medical attention.

**How do I use the FORADIL\* inhaler and capsules?**

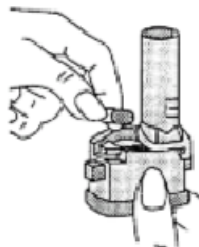
1. Pull off cap



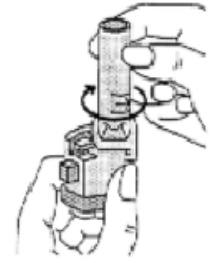
2. To open, hold base of the inhaler firmly and turn the mouthpiece in the direction of the arrow.



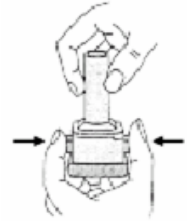
3. Remove the capsule from the blister pack. It is important to keep the capsule in the blister pack until you are ready to use it. Place the capsule in the capsule shaped compartment in the base of the inhaler.



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.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

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 perform blood tests and will interpret the results.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Allergic Reaction:</b> fainting, due to low blood pressure, rash, or itching, or swelling of the face, mouth or throat			X
<b>High Blood Pressure:</b> headache and dizziness			X
<b>Increased Blood Sugar:</b> frequent urination, thirst, and hunger		X	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Uncommon</b> Bronchospasm with wheezing or coughing and difficulty in breathing, immediately after taking your dose  <b>Serious Asthma Attacks:</b> severe increase in shortness of breath, cough, wheezing, or chest tightness which can result in hospitalization			X
			X
<b>Rare</b> <b>Decreased level of potassium in the blood:</b> irregular heartbeats, muscle weakness and generally feeling unwell		X	
<b>Very rare</b> Fast and irregular heartbeat  <b>Angina Pectoris:</b> Crushing pain in chest			X
			X

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.

*This is not a complete list of side effects. For any unexpected effects while taking Foradil\*, contact your doctor or pharmacist.*

**HOW TO STORE IT**

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.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways.

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:  
<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:  
Novartis Pharmaceuticals Canada Inc.  
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\*FORADIL is a registered trademark.