



## Patient Information Sheet

### Formoterol fumarate inhalation powder (marketed as Foradil Aerolizer)

This is a summary of the most important information about Foradil Aerolizer. For details, talk to your healthcare professional.

#### What Is Foradil Aerolizer?

Foradil Aerolizer is a medicine called a “long-acting beta-agonist” and is a long-acting bronchodilator medicine. Bronchodilator medicines help to relax the muscles around the airways in your lungs. Wheezing happens when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right away.

Foradil Aerolizer **does not** relieve sudden breathing problems. Always have a short-acting bronchodilator medicine with you to treat sudden breathing problems.

Foradil Aerolizer is used for:

#### Asthma

Foradil Aerolizer is used long-term, twice-a-day, to control and prevent symptoms of asthma in adults and children ages 5 and older.

- **Because LABA medicines such as Foradil Aerolizer may increase the chance of death from asthma problems, it is not for adults and children with asthma who:**
  - are well controlled with other asthma-controller medicines such as low-to-medium doses of inhaled corticosteroids
  - need only short-acting bronchodilators once in awhile

#### Exercise-Induced Bronchospasm (EIB)

Foradil Aerolizer is used to prevent wheezing (bronchospasm) during exercise in adults and children 5 years of age and older.

#### Chronic Obstructive Pulmonary Disease (COPD)

Foradil Aerolizer is used long-term, twice-a-day in controlling wheezing (bronchospasm) in adults with COPD.

#### What Are The Risks?

*The following are the major potential risks and side effects of Foradil Aerolizer therapy. However, this list is not complete.*

#### **Foradil Aerolizer may worsen your breathing problems.**

Long-acting beta-adrenergic agonists, such as formoterol, the active ingredient in Foradil Aerolizer, may increase the chance of death from asthma problems in some people. The package insert

(labeling) for Foradil Aerolizer has been revised to include a Medication Guide (FDA-approved patient information) which contains information about these risks (see <http://www.fda.gov/cder/drug/infopage/LABA/default.htm>).

#### **Other possible side effects with Foradil Aerolizer include:**

- allergic reactions including, rash, hives, and swelling of the face, mouth, and tongue
- increased blood pressure
- fast and irregular heartbeat
- chest pain
- headache
- tremor
- nervousness
- dry mouth
- muscle cramps
- nausea
- dizziness, tiredness
- low blood potassium
- high blood sugar
- trouble sleeping

Tell your healthcare professional about any side effect that bothers you or that does not go away.

#### What Should I Tell My Healthcare Professional?

**Before you start using Foradil Aerolizer**, tell your healthcare professional if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- are pregnant or planning to become pregnant. It is not known if Foradil Aerolizer may harm your unborn baby.
- are breastfeeding. It is not known if Foradil Aerolizer passes into your milk and if it can harm your baby.

#### Can Other Medicines or Food Affect Foradil Aerolizer?

Foradil Aerolizer and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.





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#### How Do I Use Foradil Aerolizer?

**Read the step-by-step instructions for “How to Use Foradil Aerolizer” that comes with the medicine.** Do not use Foradil Aerolizer unless your healthcare professional has taught you and you understand everything.

Use Foradil Aerolizer exactly as prescribed. Do not use Foradil Aerolizer more often than prescribed.

- Do not use a spacer device with Foradil Aerolizer. Do not breathe into the Aerolizer inhaler.
- Do not use other medicines that contain a long-acting beta<sub>2</sub>agonist or LABA for any reason.
- Do not change or stop any of your medicines to control or treat your breathing problems. Your healthcare professional will adjust your medicines as needed.
- Make sure you always have a short-acting bronchodilator medicine with you. Use your short-acting bronchodilator if you have breathing problems between doses of Foradil Aerolizer.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Foradil Aerolizer
- you need to use your short-acting bronchodilator more often
- your short-acting bronchodilator does not work as well for you at relieving symptoms
- you need to use 4 or more inhalations of your short-acting bronchodilator for 2 or more days in a row
- you use 1 whole canister of your short-acting bronchodilator medicine in less than 8 weeks time
- your peak flow meter results decrease
- your asthma symptoms do not improve after using Foradil Aerolizer for 1 week.

