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PATIENT INFORMATION
Formoterol Fumarate Inhalation Solution
(for moe' ter ol fue' ma rate)

What is formoterol fumarate inhalation solution?

- Formoterol fumarate inhalation solution is a long-acting beta₂ adrenergic agonist (LABA) used to control the symptoms of COPD in adults with COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.
- **Formoterol fumarate inhalation solution is only for use with a nebulizer.**
- LABA medicines such as formoterol fumarate inhalation solution help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.
- Formoterol fumarate inhalation solution is for long-term use and should be taken 2 times each day, to improve the symptoms of COPD for better breathing.
- **Formoterol fumarate inhalation solution is not used to treat sudden symptoms of COPD.**
- **Formoterol fumarate inhalation solution is not for the treatment of asthma. It is not known if formoterol fumarate inhalation solution is safe and effective in people with asthma.**
- **Formoterol fumarate inhalation solution should not be used in children.** It is not known if formoterol fumarate inhalation solution is safe and effective in children.

- **Do not use formoterol fumarate inhalation solution if you have asthma.**

Before using formoterol fumarate inhalation solution tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have high blood pressure
- have diabetes
- have seizures
- have thyroid problems
- have liver problems
- are pregnant or plan to become pregnant. It is not known if the medicine formoterol in formoterol fumarate inhalation solution passes into breast milk and if it can harm your baby.
- are breastfeeding or plan to breastfeed. It is not known if the medicine formoterol in formoterol fumarate inhalation solution passes into breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements. Formoterol fumarate inhalation solution and certain other medicines may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use formoterol fumarate inhalation solution?

Read the step-by-step instructions for using formoterol fumarate inhalation solution at the end of this Patient Information leaflet.

- Use formoterol fumarate inhalation solution exactly as prescribed. One-unit dose vial of formoterol fumarate inhalation solution is one dose. The usual dose of formoterol fumarate

inhalation solution is 1-unit dose vial, 2 times each day (morning and evening) breathed in through your nebulizer machine. The 2 doses should be about 12 hours apart. **Do not use more than 2 vials of formoterol fumarate inhalation solution a day.**

- Do not mix other medicines with formoterol fumarate inhalation solution in your nebulizer machine.
- If you miss a dose of formoterol fumarate inhalation solution, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- While you are using formoterol fumarate inhalation solution 2 times each day:
 - **do not use** other medicines that contain a long-acting beta₂-agonist (LABA) for any reason.
 - **do not use** your short-acting beta₂-agonist medicine on regular basis (four times a day).
- **Formoterol fumarate inhalation solution does not relieve sudden symptoms of COPD.** Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have a rescue inhaler medicine, call your healthcare provider to have one prescribed for you.
- Do not stop using **formoterol fumarate inhalation solution** or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **Do not use formoterol fumarate inhalation solution:**
 - **more often than prescribed,**
 - **more medicine than prescribed for you, or**
 - **with other LABA medicines**

Call your healthcare provider or get emergency medical care right away if your breathing problems worsen with formoterol fumarate inhalation solution, you need to use your rescue medicine more often than usual, or your rescue medicine does not work as well for you to relieve your symptoms.

What are the possible side effects of formoterol fumarate inhalation solution?

Formoterol fumarate inhalation solution can cause serious side effects, including:

- **people with asthma who take long-acting beta₂ adrenergic agonist (LABA) medicines, such as formoterol fumarate inhalation solution, without also using a medicine called an inhaled corticosteroid, have an increased risk of serious problems from asthma, including being hospitalized, needing a tube placed in their airway to help them breathe, or death.**
 - **Call your healthcare provider if breathing problems worsen over time while using formoterol fumarate inhalation solution.** You may need a different treatment.
 - **Get emergency medical care if:**
 - breathing problems worsen quickly
 - you use your rescue inhaler medicine, but it does not relieve your breathing problems
- **COPD symptoms that get worse over time.** If your COPD symptoms worsen over time, do not increase your dose of formoterol fumarate inhalation solution, instead call your healthcare provider.
- **using too much of a LABA medicine may cause:**

○ chest pain	○ increased blood pressure
○ fast and irregular heartbeat	○ headache
○ tremor	○ nervousness

- **sudden shortness of breath immediately after use of formoterol fumarate inhalation solution.** Sudden shortness of breath may be life-threatening. If you have sudden breathing problems immediately after inhaling your medicine, call your healthcare provider or go to nearest hospital emergency room right away.
- **effects on your heart**, including fast or irregular heartbeat, chest pain or increased blood pressure.
- **changes in laboratory levels**, including high levels of blood sugar (hyperglycemia) and low levels of potassium (hypokalemia), which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm.
- **serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems.** Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.

Common side effects of formoterol fumarate inhalation solution include:

- | | | | |
|-----------------|-------------|--------------------|-------------|
| • headache | • tremor | • nervousness | • dry mouth |
| • muscle cramps | • nausea | • vomiting | • diarrhea |
| • dizziness | • tiredness | • trouble sleeping | |

Tell your healthcare provider if you get any side effect that bothers you or that does not go away. These are not all the possible side effects of formoterol fumarate inhalation solution. For more information, ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store formoterol fumarate inhalation solution?

- Store formoterol fumarate inhalation solution in a refrigerator between 36° to 46°F (2° to 8°C) in the protective foil pouch. Protect from light and heat. **Do not open a sealed pouch until you are ready to use a dose of formoterol fumarate inhalation solution. After a sealed pouch is opened, formoterol fumarate inhalation solution must be used right away.** Formoterol fumarate inhalation solution may be used directly from the refrigerator.
- Formoterol fumarate inhalation solution may also be stored at room temperature between 68°F to 77°F (20° to 25°C) for up to 3 months (90 days). If stored at room temperature, discard formoterol fumarate inhalation solution if it is not used after 3 months or if past the expiration date, whichever is sooner. Space is provided on the packaging to record dispense date and use by date.
- Do not use formoterol fumarate inhalation solution after the expiration date provided on the foil pouch and vial.
- Formoterol fumarate inhalation solution should be colorless. Discard formoterol fumarate inhalation solution if it is not colorless.

Keep formoterol fumarate inhalation solution and all medicines out of the reach of children.

General information about the safe and effective use of formoterol fumarate inhalation solution.

Medicines are sometimes prescribed for purposes that are not listed in a Patient Information leaflet. Do not use formoterol fumarate inhalation solution for a condition for which it was not

prescribed. Do not give formoterol fumarate inhalation solution to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your health care provider or pharmacist for information about formoterol fumarate inhalation solution that is written for health professionals.

What are the ingredients in formoterol fumarate inhalation solution?

Active ingredient: formoterol

Inactive ingredients: sodium chloride, citric acid and sodium citrate

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

This Patient Information has been approved by the U.S. Food and Drug Administration

Instructions for Using Formoterol Fumarate Inhalation Solution

Formoterol fumarate inhalation solution is used only in a standard jet nebulizer machine connected to an air compressor. Make sure you know how to use your nebulizer machine before you use it to breathe in formoterol fumarate inhalation solution or other medicines.

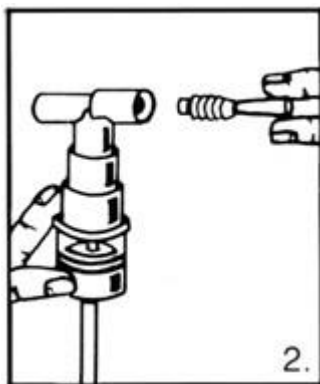
Do not mix formoterol fumarate inhalation solution with other medicines in your nebulizer machine.

Formoterol fumarate inhalation solution comes sealed in a foil pouch. Do not open a sealed pouch until you are ready to use a dose of formoterol fumarate inhalation solution.

1. Remove vial from the foil pouch.
2. Twist the cap completely off the vial and squeeze all the medicine into the nebulizer medicine cup (reservoir) (Figure 1).



3. Connect the nebulizer reservoir to the mouthpiece or facemask (Figure 2).



4. Connect the nebulizer to the compressor.
5. Sit in a comfortable, upright position. Place the mouthpiece in your mouth (Figure 3) or put on the facemask (Figure 4); and turn on the compressor.



6. Breathe as calmly, deeply and evenly as possible through your mouth until no more mist is formed in the nebulizer reservoir. The average nebulization time is 9 minutes. At this point, the treatment is finished.
7. Discard the formoterol fumarate inhalation solution container and top after use.
8. Clean the nebulizer (see manufacturer's instructions).

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

May 2021