

## **MEDICATION GUIDE**

### **PERFOROMIST® (Per-FOR-o-mist) (formoterol fumarate) Inhalation Solution**

**PERFOROMIST Inhalation Solution is only for use with a nebulizer.**

Read the Medication Guide that comes with PERFOROMIST Inhalation Solution before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

**What is the most important information I should know about PERFOROMIST Inhalation Solution?**

**PERFOROMIST Inhalation Solution can cause serious side effects including:**

- **People with asthma who take long-acting beta<sub>2</sub> adrenergic agonist (LABA) medicines such as PERFOROMIST Inhalation Solution have an increased risk of death from asthma problems.**
- It is not known if LABA medicines, such as PERFOROMIST Inhalation Solution, increase the risk of death in people with chronic obstructive pulmonary disease (COPD).
- **Get emergency medical care if:**
  - **breathing problems worsen quickly**
  - **you use your rescue inhaler medicine, but it does not relieve your breathing problems**

**What is PERFOROMIST Inhalation Solution?**

**PERFOROMIST Inhalation Solution is used long term, 2 times a day (morning and evening), in controlling symptoms of chronic obstructive pulmonary disease (COPD) in adults with COPD.**

**PERFOROMIST Inhalation Solution is only for use with a nebulizer.** LABA medicines such as PERFOROMIST 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.

PERFOROMIST Inhalation Solution is not for use to treat sudden symptoms of COPD.

**PERFOROMIST Inhalation Solution should not be used in children. It is not known if PERFOROMIST Inhalation Solution is safe and effective in children.**

**It is not known if PERFOROMIST Inhalation Solution is safe and effective in people with asthma.**

**Who should not use PERFOROMIST Inhalation Solution?**

**Do not use PERFOROMIST Inhalation Solution if you have asthma without using a long-term asthma control medicine.**

**What should I tell my healthcare provider before using PERFOROMIST Inhalation Solution?**

**Tell your healthcare provider about all of your health conditions, including if you:**

- **have heart problems**
- **have high blood pressure**
- **have diabetes**
- **have seizures**
- **have thyroid problems**
- **have liver problems**
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**are pregnant or planning to become pregnant.** It is not known if PERFOROMIST Inhalation Solution can harm an unborn baby.

- **are breastfeeding.** It is not known if PERFOROMIST 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 non-prescription medicines, vitamins and herbal supplements.** PERFOROMIST 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 PERFOROMIST Inhalation Solution?**

**Read the step-by-step instructions for using PERFOROMIST Inhalation Solution at the end of this Medication Guide.**

- Use PERFOROMIST Inhalation Solution exactly as prescribed. One ready-to-use vial of PERFOROMIST Inhalation Solution is one dose. The usual dose of PERFOROMIST Inhalation Solution is one ready-to-use vial, twice a 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 PERFOROMIST Inhalation Solution a day.**
- Do not mix other medicines with PERFOROMIST Inhalation Solution in your nebulizer machine.
- If you miss a dose of PERFOROMIST 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 PERFOROMIST Inhalation Solution 2 times each day:
  - **do not use** other medicines that contain a long-acting beta  $\beta_2$ -agonist (LABA) for any reason.
  - **do not use** your short-acting beta  $\beta_2$ -agonist medicine on a regular basis (four times a day).
- **PERFOROMIST 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 **PERFOROMIST 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 PERFOROMIST 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 PERFOROMIST Inhalation Solution
- you need to use your rescue inhaler medicine more often than usual
- your rescue inhaler medicine does not work as well for you at relieving symptoms

**What are the possible side effects of PERFOROMIST Inhalation Solution?**

**PERFOROMIST Inhalation Solution can cause serious side effects, including:**

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See “What is the most important information I should know about PERFOROMIST Inhalation Solution?”

- **Sudden shortness of breath immediately after use of PERFOROMIST Inhalation Solution.**
- **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.
- **chest pain**
- **increased or decreased blood pressure**
- **a fast and irregular heartbeat**
- **low blood potassium**
- **high blood sugar**
- **high blood acid**

**Common side effects of PERFOROMIST Inhalation Solution include:**

- **headache**
- **tremor**
- **nervousness**
- **dry mouth**
- **muscle cramps**
- **nausea, vomiting**
- **diarrhea**
- **dizziness**
- **tiredness**
- **trouble sleeping**
- **If your COPD symptoms worsen over time do not increase your dose of PERFOROMIST Inhalation Solution, instead call your healthcare provider.**

Tell your healthcare provider if you get any side effect that bothers you or that does not go away.

These are not all the side effects with PERFOROMIST Inhalation Solution. 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 PERFOROMIST Inhalation Solution?**

- Store PERFOROMIST 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 PERFOROMIST Inhalation Solution. Once a sealed pouch is opened, PERFOROMIST Inhalation Solution must be used right away.** PERFOROMIST Inhalation Solution may be used directly from the refrigerator.
- PERFOROMIST Inhalation Solution may also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 3 months (90 days). If stored at room temperature, discard PERFOROMIST 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 PERFOROMIST Inhalation Solution after the expiration date provided on the foil pouch and vial.
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PERFOROMIST Inhalation Solution should be colorless. Discard PERFOROMIST Inhalation Solution if it is not colorless.

- **Keep PERFOROMIST Inhalation Solution and all medicines out of the reach of children.**

### **General Information about PERFOROMIST Inhalation Solution**

Medicines are sometimes prescribed for purposes that are not mentioned in a Medication Guide. Do not use PERFOROMIST Inhalation Solution for a condition for which it was not prescribed. Do not give PERFOROMIST Inhalation Solution to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about PERFOROMIST Inhalation Solution. If you would like more information, talk with your health care provider. You can ask your health care provider or pharmacist for information about PERFOROMIST Inhalation Solution that was written for health care professionals.

- For customer service, call 1-800-395-3376
- To report side effects and for medical information, call 1-877-446-3679

### **Instructions for Using PERFOROMIST (formoterol fumarate) Inhalation Solution**

**PERFOROMIST 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 PERFOROMIST Inhalation Solution or other medicines.**

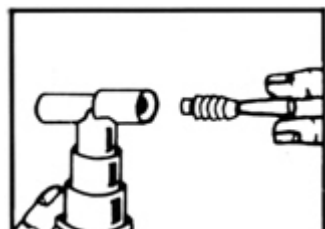
**Do not mix PERFOROMIST Inhalation Solution with other medicines in your nebulizer machine.**

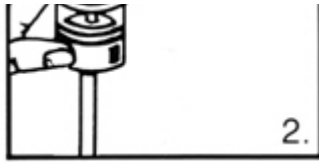
PERFOROMIST Inhalation Solution comes sealed in a foil pouch. Do not open a sealed pouch until you are ready to use a dose of PERFOROMIST Inhalation Solution.

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).

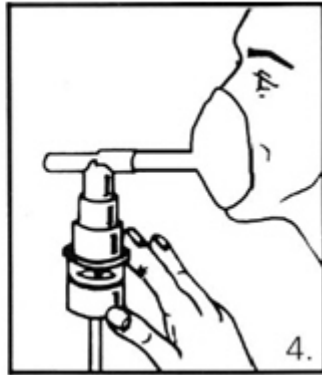


3. Connect the nebulizer reservoir to the mouthpiece or facemask (Figure 2).





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 PERFOROMIST Inhalation Solution container and top after use.
8. Clean the nebulizer (see manufacturer's instructions).

Manufactured for:

**Mylan Specialty L.P.**

Morgantown, WV 26505 U.S.A.

Manufactured by:

**The Ritedose Corporation**

Columbia, SC 29203 U.S.A.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: 3/2018

MG:FORMIS:R2