

their symptoms worsen despite recommended doses of PERFOROMIST Inhalation Solution, if PERFOROMIST Inhalation Solution treatment becomes less effective, or if they need more inhalations of a short-acting beta₂-agonist than usual.

Appropriate Dosing

Patients should not stop using PERFOROMIST Inhalation Solution unless told to do so by a healthcare provider because symptoms may get worse. Patients should not inhale more than the prescribed number of vials at any one time. The daily dosage of PERFOROMIST Inhalation Solution should not exceed one vial twice daily (40 mcg total daily dose). Excessive use of sympathomimetics may cause significant cardiovascular effects, and may be fatal.

Concomitant Therapy

Patients who have been taking inhaled, short-acting beta₂-agonists (e.g., albuterol) on a regular basis should be instructed to discontinue the regular use of these products and use them only for symptomatic relief of acute symptoms. PERFOROMIST Inhalation Solution should not be used in conjunction with other inhaled medications containing long-acting beta₂-agonists. Patients should be warned not to stop or change the dose of other concomitant COPD therapy without medical advice, even if symptoms improve after initiating treatment with PERFOROMIST Inhalation Solution.

Common Adverse Reactions with Beta₂-agonists

Patients should be informed that treatment with beta₂-agonists may lead to adverse reactions that include palpitations, chest pain, rapid heart rate, increased or decreased blood pressure, headache, tremor, nervousness, dry mouth, muscle cramps, nausea, dizziness, fatigue, malaise, low blood potassium, high blood sugar, high blood acid, or trouble sleeping [see ADVERSE REACTIONS (6.1)].

Instructions for Administration

It is important that patients understand how to use PERFOROMIST Inhalation Solution with a nebulizer appropriately [see the accompanying Medication Guide]. Patients should be instructed not to mix other medications with PERFOROMIST Inhalation Solution or ingest PERFOROMIST Inhalation Solution. Patients should throw the plastic dispensing container away immediately after use. Due to their small size, the container and top pose a danger of choking to young children.

FDA-Approved Medication Guide

See the accompanying Medication Guide.

Dey®

Dey Pharma, L.P., Napa, CA 94558

U.S. Pat. No. 6,667,344

U.S. Pat. No. 6,814,953

03-848-XX

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 beta₂ 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**
- **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 beta₂-agonist (LABA) for any reason.
 - **do not use** your short-acting beta₂-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:

- 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.
- 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 healthcare professionals.

- For customer service, call 1-800-395-3376
- To report side effects, call (1-877-446-3679)
- For medical information, call 1-800-429-7751

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.

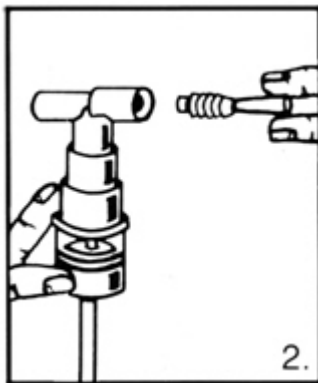
Do not mix PERFOROMIST Inhalation Solution with other medicines in your nebulizer machine.

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.

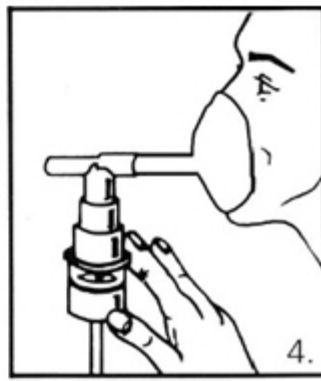
1. Remove vial from the foil pouch.
2. Twist the cap completely off the vial and squeeze all the medicine into the nebulizer medicine cup (reservoir) (Figure 1).



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).

Dey Pharma, L.P.

Napa, CA 94558 U.S.A.

Revised MM YYYY

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

03-848-0X

PRINCIPAL DISPLAY PANEL - 20 mcg/2 mL vial

NDC 49502-605-61

Perforomist[®]

(formoterol fumarate) INHALATION SOLUTION

20 mcg/2 mL vial

Medication Guide For Patients Enclosed

Sterile Unit Dose Vials - Individually Wrapped - For Oral Inhalation Only

CARTON CONTAINS: 60 individually wrapped 2 mL vials

EACH 2 mL VIAL CONTAINS: ACTIVE: Formoterol fumarate, USP.

INACTIVES: Citric acid, sodium citrate, sodium chloride, and water.

STORAGE CONDITIONS:

PRIOR TO DISPENSING TO THE PATIENT: Store refrigerated, 2°C to 8°C (36°F to 46°F).

AFTER DISPENSING TO THE PATIENT: Store at 2°C to 25°C (36°F to 77°F) for up to 3 months.

Protect pouch from heat. **VIAL SHOULD ALWAYS BE STORED IN THE FOIL POUCH, AND ONLY REMOVED IMMEDIATELY BEFORE USE.**

Keep out of reach of children.

FOR THE HEALTHCARE PROVIDER: When Perforomist[®] Inhalation Solution is dispensed to the patient, write an expiration date in the "Use

by" box on the carton or dispensing container. The date should not exceed either 3 months from date dispensed or the expiration date on

the product, whichever comes first. After dispensing to the patient, store at 2°C to 25°C (36°F to 77°F) for up to 3 months.

FOR THE PATIENT: Use Perforomist[®] Inhalation Solution prior to the "Use by" date.

Rx Only

U.S. Pat. Nos. 6,667,344 and 6,814,953

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