



**Ipratropium Bromide and
Albuterol Sulfate Inhalation
Solution 0.5 mg/3 mg, USP**

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**Ipratropium Bromide
(IH-pruh-TROE-pee-uhm BROE-mide)
and Albuterol Sulfate (al-BUE-ter-ol)
Inhalation Solution, USP 0.5 mg/3 mg**

***Equivalent to 2.5 mg albuterol base**

Patient's Instructions for Use

Read this patient information completely every time your prescription is filled as information may have changed. Keep these instructions with your medication as you may want to read them again.

Ipratropium bromide and albuterol sulfate inhalation solution should only be used under the direction of a physician. Your physician and pharmacist have more information about ipratropium bromide and albuterol sulfate inhalation solution and the condition for which it has been prescribed. Contact them if you have additional questions.

Storing your Medicine

Store ipratropium bromide and albuterol sulfate inhalation solution at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). Protect from light. Unit dose vials should remain stored in the protective foil pouch at all times. Once removed from the foil pouch, the individual vials should be used within one week. Discard if solution is not colorless. Do not use after the expiration (EXP) date printed on the carton.

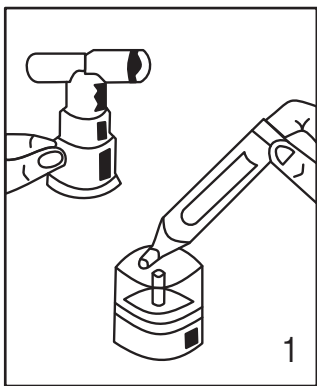
Dose

Ipratropium bromide and albuterol sulfate inhalation solution is supplied as a single-dose, ready-to-use vial containing 3 mL of solution. No mixing or dilution is needed. Use one new vial for each nebulizer treatment.

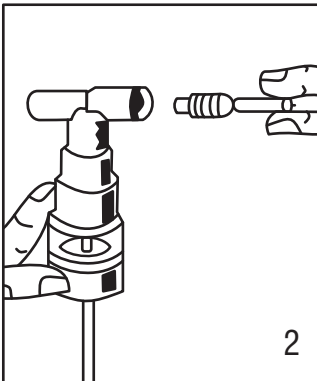
FOLLOW THESE DIRECTIONS FOR USE OF YOUR NEBULIZER/COMPRESSOR OR THE DIRECTIONS GIVEN BY YOUR HEALTHCARE PROVIDER. A TYPICAL EXAMPLE IS SHOWN BELOW.

Instructions for Use

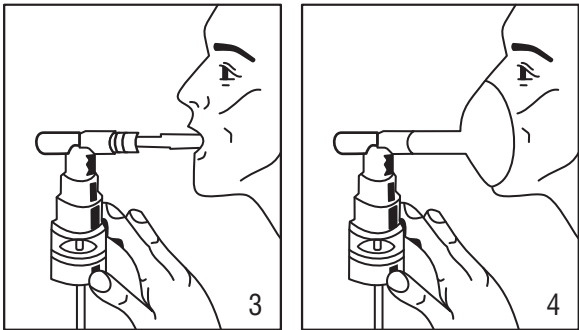
1. Remove one vial from the foil pouch. Place remaining vials back into pouch for storage.
2. Twist the cap completely off the vial and squeeze the contents into the nebulizer reservoir (Figure 1).



3. Connect the nebulizer to the mouthpiece or face mask (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 face mask (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 chamber (about 5 to 15 minutes). At this point, the treatment is finished.
7. Clean the nebulizer (see manufacturer's instructions).

Patient Information

**Ipratropium Bromide
(IH-pruh-TROE-pee-uhm BROE-mide)
and Albuterol Sulfate (al-BUE-ter-ol)
Inhalation Solution, USP 0.5 mg/3 mg**

***Equivalent to 2.5 mg albuterol base**

Prescription Only.

Read the patient information that comes with ipratropium bromide and albuterol sulfate inhalation solution before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is ipratropium bromide and albuterol sulfate inhalation solution?

Ipratropium bromide and albuterol sulfate inhalation solution is a combination of two medicines called bronchodilators. Ipratropium bromide and albuterol sulfate inhalation solution contains albuterol sulfate, which is a beta-adrenergic agonist, and ipratropium bromide, which is an anticholinergic. These two medicines work together to help open the airways in your lungs. Ipratropium bromide and albuterol sulfate inhalation solution is used to help treat airway narrowing (bronchospasm) that happens with chronic obstructive pulmonary disease (COPD) in adult patients who need to use more than one bronchodilator medicine.

Who should not use ipratropium bromide and albuterol sulfate inhalation solution?

Do not use ipratropium bromide and albuterol sulfate inhalation solution if you: Are allergic to any of the ingredients in ipratropium bromide and albuterol sulfate inhalation solution or to atropine. The active ingredients are albuterol sulfate and ipratropium bromide. See the end of this leaflet for a complete list of ingredients in ipratropium bromide and albuterol sulfate inhalation solution.

Ipratropium bromide and albuterol sulfate inhalation solution has not been studied in patients younger than 18 years of age.

What should I tell my doctor before I start using ipratropium bromide and albuterol sulfate inhalation solution?

Tell your doctor about all of your conditions, including if you:

- Have heart problems. This includes coronary artery disease and heart rhythm problems.
- Have high blood pressure

- Have diabetes
- Have or had seizures
- Have a thyroid problem called hyperthyroidism
- Have an eye problem called narrow-angle glaucoma
- Have liver or kidney problems
- Have problems urinating due to bladder-neck blockage or an enlarged prostate (men)
- Are pregnant or planning to become pregnant. It is not known if ipratropium bromide and albuterol sulfate inhalation solution can harm your unborn baby. You and your doctor will have to decide if ipratropium bromide and albuterol sulfate inhalation solution is right for you during a pregnancy.
- Are breastfeeding. It is not known if ipratropium bromide and albuterol sulfate inhalation solution passes into your milk or if it can harm your baby. You and your doctor should decide whether you should take ipratropium bromide and albuterol sulfate inhalation solution or breastfeed, but not both.

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. Ipratropium bromide and albuterol sulfate inhalation solution and other medicines can interact. This may cause serious side effects. Especially tell your doctor if you take:

- Other medicines that contain anticholinergics such as ipratropium bromide. This also includes medicines used for Parkinson's disease.
- Other medicines that contain beta-agonists such as albuterol sulfate. These are usually used to treat airway narrowing (bronchospasm).
- Medicines called beta-blockers. These are usually used for high blood pressure or heart problems.
- Medicines called "water pills" (diuretics)
- Medicines for depression called monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants.

Ask your doctor or pharmacist if you are not sure if you take any of these types of medicines. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacists when you get a new medicine.

How should I use ipratropium bromide and albuterol sulfate inhalation solution?

- Read the Patient's Instructions for Use that you get with your prescription. Talk to your doctor or pharmacist if you have any questions.
- Take ipratropium bromide and albuterol sulfate inhalation solution exactly as prescribed by your doctor. Do not change your dose or how often you use ipratropium bromide and albuterol sulfate inhalation solution without talking to your doctor. Inhale ipratropium bromide and albuterol sulfate inhalation solution through your mouth and into your lungs using a machine called a nebulizer.
- Ipratropium bromide and albuterol sulfate inhalation solution may help to open your airways for up to 5 hours after taking this medicine. If ipratropium bromide and albuterol sulfate inhalation solution does not help your airway narrowing (bronchospasm) or your bronchospasm gets worse, call your doctor right away or get emergency help if needed.

What should I avoid while using ipratropium bromide and albuterol sulfate inhalation solution?

Do not get ipratropium bromide and albuterol sulfate inhalation solution in your eyes. Be careful not to spray ipratropium bromide and albuterol sulfate inhalation solution in your eyes while you are using your nebulizer. Ipratropium bromide and albuterol sulfate inhalation solution can cause the following short-term eye problems:

- Enlarged pupils
- Blurry vision
- Eye pain

Front Side 248 mm

**Folding
248---1---124 mm
375---4---23.4 mm**

Actual Size: 248x375 mm

375 mm

Ipratropium bromide and albuterol sulfate inhalation solution can cause a serious eye problem called narrow-angle glaucoma or worsen the narrow-angle glaucoma you already have.

What are the possible side effects with ipratropium bromide and albuterol sulfate inhalation solution?

Ipratropium bromide and albuterol sulfate inhalation solution may cause the following serious side effects:

- **Worsening of the narrowing in your airways (bronchospasm).** This side effect can be life-threatening and has happened with both of the medicines that are in ipratropium bromide and albuterol sulfate inhalation solution. Stop ipratropium bromide and albuterol sulfate inhalation solution and call your doctor right away or get emergency help if your breathing problems get worse while or after using ipratropium bromide and albuterol sulfate inhalation solution.
- **Serious and life-threatening allergic reactions. Symptoms of a serious allergic reaction include:**
 - Hives, rash
 - Swelling of your face, eyelids, lips, tongue, or throat, and trouble swallowing
 - Worsening of your breathing problems such as wheezing, chest tightness or shortness of breath
 - Shock (loss of blood pressure and consciousness)

The most common side effects with ipratropium bromide and albuterol sulfate inhalation solution include lung disease, sore throat, chest pain, constipation, diarrhea, bronchitis, urinary tract infection, leg cramps, nausea, upset stomach, voice changes, and pain.

These are not all the side effects with ipratropium bromide and albuterol sulfate inhalation solution. For a complete list, ask your doctor or pharmacist.

How should I store ipratropium bromide and albuterol sulfate inhalation solution?

- Store ipratropium bromide and albuterol sulfate inhalation solution at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). Protect from light. Unit dose vials should remain stored in the protective foil pouch at all times. Once removed from the foil pouch, the individual vials should be used within one week. Discard if solution is not colorless.
- Safely discard ipratropium bromide and albuterol sulfate inhalation solution that is out-of-date or no longer needed.
- Keep ipratropium bromide and albuterol sulfate inhalation solution and all medicines out of the reach of children.

General advice about Ipratropium Bromide and Albuterol Sulfate Inhalation Solution

Medicines are sometimes prescribed for conditions that are not mentioned in the patient information leaflets. Do not use ipratropium bromide and albuterol sulfate inhalation solution for a condition for which it was not prescribed. Do not give ipratropium bromide and albuterol sulfate inhalation solution to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ipratropium bromide and albuterol sulfate inhalation solution. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ipratropium bromide and albuterol sulfate inhalation solution that is written for healthcare professionals.

What are the ingredients in ipratropium bromide and albuterol sulfate inhalation solution?

Active Ingredients: ipratropium bromide, USP and albuterol sulfate, USP

Inactive Ingredients: sodium chloride, hydrochloric acid, edetate sodium, USP and water for injection.

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

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