

Patient Information

DuoNeb[®] (DOO-o-neb)
(Ipratropium Bromide 0.5 mg/Albuterol Sulfate 3.0 mg*) Inhalation Solution
***Equivalent to 2.5 mg albuterol base**

Prescription Only.

Read the patient information that comes with DuoNeb[®] 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 DuoNeb[®]?

DuoNeb[®] is a combination of two medicines called bronchodilators. DuoNeb[®] 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. DuoNeb[®] 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 DuoNeb[®]?

Do not use DuoNeb[®] if you: Are allergic to any of the ingredients in DuoNeb 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 DuoNeb[®].

DuoNeb[®] has not been studied in patients younger than 18 years of age.

What should I tell my doctor before I start using DuoNeb[®]?

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 DuoNeb[®] can harm your unborn baby. You and your doctor will have to decide if DuoNeb[®] is right for you during a pregnancy.
- Are breastfeeding. It is not known if DuoNeb[®] passes into your milk or if it can harm your baby. You and your doctor should decide whether you should take DuoNeb[®] or breastfeed, but not both.

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. DuoNeb[®] 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 DuoNeb[®]?

- 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 DuoNeb[®] exactly as prescribed by your doctor. Do not change your dose or how often you use DuoNeb[®] without talking to your doctor. Inhale DuoNeb[®] through your mouth and into your lungs using a machine called a nebulizer.
- DuoNeb[®] may help to open your airways for up to 5 hours after taking this medicine. If DuoNeb[®] 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 DuoNeb®?

Do not get DuoNeb® in your eyes. Be careful not to spray DuoNeb® in your eyes while you are using your nebulizer. DuoNeb® can cause the following short-term eye problems:

- Enlarged pupils
- Blurry vision
- Eye pain

DuoNeb® 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 DuoNeb®?

DuoNeb® 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 DuoNeb®. Stop DuoNeb® and call your doctor right away or get emergency help if your breathing problems get worse while or after using DuoNeb®.
- **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 DuoNeb® 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 DuoNeb®. For a complete list, ask your doctor or pharmacist.

How should I store DuoNeb®?

- Store DuoNeb® between 36° and 86°F (2° and 30°C). Protect from light. Keep the unused vials in the foil pouch or carton.
- Safely discard DuoNeb® that is out-of-date or no longer needed.
- Keep DuoNeb® and all medicines out of the reach of children.

General advice about DuoNeb®

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

This leaflet summarizes the most important information about DuoNeb®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DuoNeb® that is written for health professionals. You can also call the company that makes DuoNeb® toll free at 1-800-755-5560 or visit their website at www.dey.com.

What are the ingredients in DuoNeb®?

Active Ingredients: ipratropium bromide and albuterol sulfate

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