

PATIENT INFORMATION

Levalbuterol (LEE-val-BUE-ter-ol) Inhalation Solution, USP 0.31 mg/3 mL, 0.63 mg/3mL and 1.25 mg/3 mL

**For Oral Inhalation Only
Levalbuterol Inhalation Solution is only
for use with a nebulizer.**

Read this Patient Information before you start to use levalbuterol inhalation solution and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is levalbuterol inhalation solution?

Levalbuterol inhalation solution is an inhaled prescription medicine used for the treatment or prevention of bronchospasm in people 6 years of age and older.

Levalbuterol inhalation solution has not been shown to be safe and effective in children younger than 6 years of age.

Levalbuterol inhalation solution is supplied in 3 mL unit-dose vials in three different strengths of levalbuterol (0.31 mg, 0.63 mg, 1.25 mg). The vials do not require dilution before use.

Who should not use levalbuterol inhalation solution?

Do not use levalbuterol inhalation solution if you are allergic to levalbuterol, racemic albuterol, or any of the ingredients in levalbuterol. See the end of this leaflet for a complete list of ingredients in levalbuterol inhalation solution.

What should I tell my doctor before using levalbuterol inhalation solution?

Before you use levalbuterol inhalation solution, tell your doctor if you have:

- had an allergic reaction to levalbuterol or racemic albuterol
- heart problems
- high blood pressure
- seizures
- diabetes
- thyroid problems
- any other medical conditions
- are pregnant or planning to become pregnant. It is not known if levalbuterol inhalation solution will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if levalbuterol passes into your breast milk. You and your doctor should decide if you will use levalbuterol inhalation solution or breastfeed. You should not do both.

Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Levalbuterol inhalation solution may affect the way other medicines work, and other medicines may affect how levalbuterol inhalation solution works.

Especially tell your doctor if you take:

- other asthma medicines
- heart medicines
- medicines that increase urination (diuretics)
- antidepressants
- medicine to treat chronic obstructive pulmonary disease (COPD)

Ask your doctor if you are not sure if any of your medicines are the kinds listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I use levalbuterol inhalation solution?

- Read the step-by-step Instructions for Using Levalbuterol Inhalation Solution at the end of this leaflet.
- Use levalbuterol inhalation solution exactly as your doctor tells you to. **Do not** change your dose without talking to your doctor first.
- Your doctor will tell you how many times and when to use your levalbuterol inhalation solution.
- An adult should help a child use levalbuterol inhalation solution.
- **Do not use your levalbuterol inhalation solution more often than your doctor tells you to.**
- **Get medical help right away if levalbuterol inhalation solution:**
 - does not work as well for your asthma symptoms or
 - your asthma symptoms get worse or
 - you need to use your levalbuterol inhalation solution more often than usual
- If you also use another medicine by inhalation, you should ask your doctor for instructions on when to use it while you are also using levalbuterol inhalation solution.
- **Do not** mix levalbuterol inhalation solution with other medicines in your nebulizer.
- **Only use levalbuterol inhalation solution if it is colorless.** Throw away the levalbuterol inhalation solution vial if the liquid medicine is not colorless.
- Do not use levalbuterol inhalation solution after the expiration date on the vial.

What are the possible side effects of levalbuterol inhalation solution?

Levalbuterol inhalation solution can cause serious side effects including:

- **sudden shortness of breath (bronchospasm).** Sudden shortness of breath can happen right away after using levalbuterol inhalation solution.
- **worsening asthma**
- **heart problems**
- **death.** If you use too much levalbuterol inhalation solution you can have heart or lung problems that can lead to death.
- **serious allergic reactions.** Call your doctor and stop using levalbuterol inhalation solution right away if you have any symptoms of an allergic reaction such as:
 - swelling of the face, throat or tongue
 - hives
 - rash
 - breathing problems
- **low potassium levels in your blood**

Call your doctor or go to the nearest hospital emergency room right away if you have any of the serious side effects listed above or if you have worsening lung symptoms.

The most common side effects of levalbuterol inhalation solution include:

- palpitations
- chest pain
- fast heart rate
- headache
- dizziness
- tremor
- nervousness

Tell your doctor if you have any side effects that bother you or that do not go away.

These are not all the possible side effects of levalbuterol inhalation solution. For more information, ask your doctor or pharmacist.

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 levalbuterol inhalation solution?

- Store unopened levalbuterol inhalation solution vials in the protective foil pouch they come in between 68°F to 77°F (20°C to 25°C).
- Keep levalbuterol inhalation solution away from light and heat.
- When a levalbuterol inhalation solution foil pouch is opened, use the vials within 2 weeks.
- When levalbuterol inhalation solution vials are removed from the foil pouch, use them right away or within 1 week.

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use levalbuterol inhalation solution for a condition for which it was not prescribed. Do not give levalbuterol inhalation solution to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about levalbuterol inhalation solution. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about levalbuterol inhalation solution that is written for health professionals.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to asthma medication, including levalbuterol inhalation solution, during pregnancy. To enroll in the Asthma & Pregnancy Study or for more information about the registry, call 1-877-311-8972 or visit www.mothersbaby.org/ongoingstudy/asthma.

For customer service, To report adverse events and For medical information: call 1-800-818-4555.

What are the ingredients in levalbuterol inhalation solution?

Active ingredient: levalbuterol hydrochloride
Inactive ingredients: sodium chloride, edetate disodium, sulfuric acid, water for injection and nitrogen

Instructions for Using Levalbuterol Inhalation Solution, USP

Levalbuterol Inhalation Solution vial
(see Figure A):

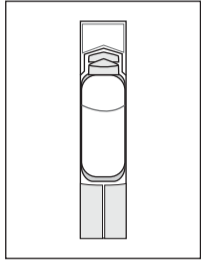


Figure A

Using your Levalbuterol Inhalation Solution:

Read the following Steps before using your levalbuterol inhalation solution. If you have any questions, ask your doctor or pharmacist.

Step 1. Open the foil pouch by tearing the notched edge along the seam of the pouch (See Figure B). Remove 1 vial to be used right away. Keep the rest of the unused vials in the foil pouch to protect them from light and heat.



Figure B

Step 2. Hold the vial in your hands. Make sure your thumb and finger cover the twist-off tabs (See Figure C).

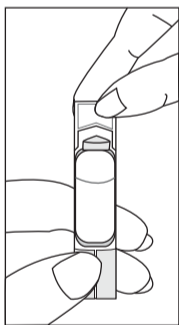


Figure C

Step 3. While holding the top firmly between your thumb and finger, twist the body of the vial to open the vial (See Figure C).

Step 4. Throw away the top of the vial and squeeze the entire contents of the vial into the nebulizer reservoir (See Figure D).

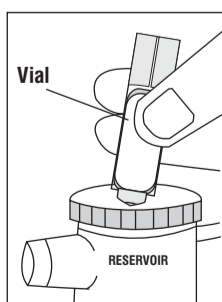


Figure D

Step 5. Connect the nebulizer reservoir to the mouthpiece (See Figure E.1) or face mask (See Figure E.2).

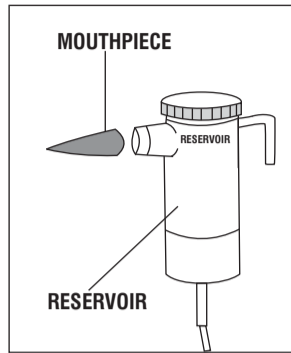


Figure E.1

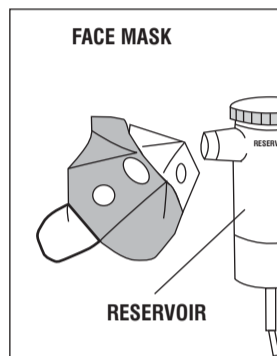


Figure E.2

Step 6. Connect the nebulizer to the compressor (See Figure F).

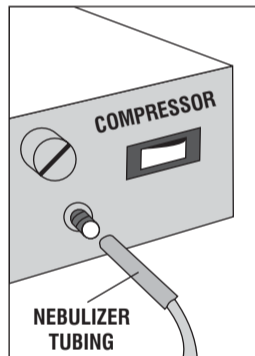


Figure F

Step 7. Sit in a comfortable, upright position. Place the mouthpiece in your mouth (See Figure G.1) or put on your face mask (See Figure G.2). Turn on the compressor.

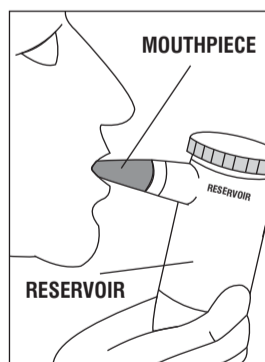


Figure G.1

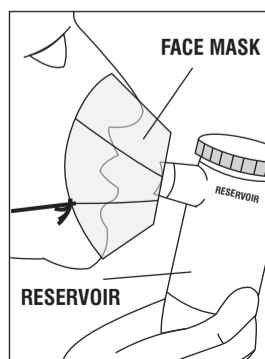


Figure G.2

Step 8. Breathe as calmly, deeply, and evenly as possible until no more mist is seen in the nebulizer reservoir. Your treatment will take about 5 to 15 minutes. When you do not see any mist in the nebulizer reservoir, your treatment is finished.

Step 9. Clean and store your nebulizer. See the manufacturer's instructions that come with your nebulizer for how to clean and store your nebulizer.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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