

PATIENT INFORMATION LEAFLET

Levalbuterol Inhalation Solution, USP

(pronounced lev" al bue' ter ol)

0.31 mg, 0.63 mg, 1.25 mg

3 mL Unit-Dose Vials

For Oral Inhalation Only

Rx only

Levalbuterol Inhalation Solution, USP is only for use with a nebulizer.

Read this Patient Information Leaflet before you start to use Levalbuterol Inhalation Solution, USP 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, USP?

Levalbuterol Inhalation Solution, USP is an inhaled prescription medicine used for the treatment or prevention of bronchospasm in people 6 years of age and older.

Levalbuterol Inhalation Solution, USP has not been shown to be safe and effective in children younger than 6 years of age.

Levalbuterol Inhalation Solution, USP 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, USP?

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

Levalbuterol Inhalation Solution, USP.

What should I tell my doctor before using Levalbuterol Inhalation Solution, USP?

Before you use Levalbuterol Inhalation Solution, USP, 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, USP 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 Inhalation Solution, USP passes into your breast milk. You and your doctor should decide if you will use Levalbuterol Inhalation Solution, USP 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, USP may affect the way other medicines work, and other medicines may affect how Levalbuterol Inhalation Solution, USP 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, USP?

- Read the step-by-step Instructions for Using Levalbuterol Inhalation Solution, USP at the end of this leaflet.
- Use Levalbuterol Inhalation Solution, USP 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, USP.

- An adult should help a child use Levalbuterol Inhalation Solution, USP.
- **Do not use your Levalbuterol Inhalation Solution, USP more often than your doctor tells you to.**
- **Get medical help right away if Levalbuterol Inhalation Solution, USP:**
 - o does not work as well for your asthma symptoms or
 - o your asthma symptoms get worse or
 - o you need to use your Levalbuterol Inhalation Solution, USP 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, USP.
- **Do not** mix Levalbuterol Inhalation Solution, USP with other medicines in your nebulizer.
- **Only use Levalbuterol Inhalation Solution, USP if it is colorless.** Throw away the Levalbuterol Inhalation Solution, USP vial if the liquid medicine is not colorless.
- Do not use Levalbuterol Inhalation Solution, USP after the expiration date on the vial.

What are the possible side effects of Levalbuterol Inhalation Solution, USP?

Levalbuterol Inhalation Solution, USP can cause serious side effects including:

- **sudden shortness of breath (bronchospasm).** Sudden shortness of breath can happen right away after using Levalbuterol Inhalation Solution, USP.
- **worsening asthma**
- **heart problems**
- **death.** If you use too much Levalbuterol Inhalation Solution, USP you can have heart or lung problems that can lead to death.
- **serious allergic reactions.** Call your doctor and stop using Levalbuterol Inhalation Solution, USP right away if you have any symptoms of an allergic reaction such as:
 - o swelling of the face, throat or tongue
 - o hives
 - o rash
 - o 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, USP 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, USP. 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, USP?

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

Keep Levalbuterol Inhalation Solution, USP and all medicines out of the reach of children.

General information about the safe and effective use of Levalbuterol Inhalation Solution, USP.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use Levalbuterol Inhalation Solution, USP for a condition for which it was not prescribed. Do not give Levalbuterol Inhalation Solution, USP 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, USP. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Levalbuterol Inhalation Solution, USP that is written for health professionals.

To report SUSPECTED ADVERSE REACTIONS, contact The Ritedose Corporation at 1-855-806-3300 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What are the ingredients in Levalbuterol Inhalation Solution, USP?

Active ingredient: levalbuterol hydrochloride

Inactive ingredients: sodium chloride, edetate disodium, sulfuric acid, and water