

Soventus[®]-LS Syrup

(Levosalbutamol, Ambroxol Hydrochloride & Guaiphenesin Syrup)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Soventus[®]-LS Syrup is and what it is used for
2. What you need to know before you take Soventus[®]-LS Syrup
3. How to take Soventus[®]-LS Syrup
4. Possible side effects
5. How to store Soventus[®]-LS Syrup
6. Contents of the pack and other Information

1. What is Soventus[®]-LS Syrup and what it is used for

Soventus[®]-LS Syrup is the combination of Levosalbutamol, Ambroxol Hydrochloride & Guaiphenesin Syrup. These active ingredients belong to a group of medicines known as bronchodilators, mucolytic and mucokinetic used to treat asthma, bronchospasm and reversible airways obstruction by widening the airways of the lungs. It is suitable for children or adults who prefer liquid medicines or are unable to use an inhaler device.

Ambroxol hydrochloride widely used as a mucolytic. It increases secretion in the respiratory tract and stimulates ciliary activity. These actions result in improved mucus flow and clearance. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and reduces cough. Levosalbutamol is used as a bronchodilator, used to treat bronchospasm and symptoms of asthma and chronic obstructive pulmonary disease (COPD), such as coughing, wheezing, and shortness of breath. It relaxes the muscles in the airways and increases airflow to the lungs. Levosalbutamol makes breathing easier by widening the airways. By bronchodilator action, it also increases mucociliary clearance, suppression of oedema and exerts anti- allergic effects. **Guaifenesin** is an expectorant that also has some muscle relaxing action. It is used in many cough preparations. This increases the flow of fluids from glands lining the respiratory tract. This results in an increase in volume and decrease in viscosity of bronchial secretions.

2. What you need to know before you take Soventus®-LS Syrup

Do not take Soventus®-LS Syrup if you:

- Hypersensitivity to any of the components of the formulation.
- Pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease.
- Gastric ulceration.

Warnings and precautions

In cases of severe renal failure, an accumulation of metabolites formed in the liver must be considered, and a reduction in the maintenance dose of Ambroxol or an increase in the dose interval must be performed. In patients with a tendency for peptic ulcers, the use of Ambroxol hydrochloride should be carefully considered.

For Levosalbutamol, caution should be observed in patients with thyrotoxicosis. Cardiovascular effects may be seen with sympathomimetic drugs, including Levosalbutamol.

Guaifenesin should not be used for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician. Caution should be exercised in the presence of severe renal or severe hepatic impairment. The concomitant use of cough suppressants is not recommended.

Other medicines and Soventus®-LS Syrup

The concomitant use of antitussives along with ambroxol may impair the coughing up of the liquefied bronchial mucous and cause a secretory obstruction.

The administration of ambroxol with antibiotics (amoxicillin, cefuroxime, and erythromycin) increases the concentration of antibiotics in bronchopulmonary secretions and sputum.

Levosalbutamol and non-selective β -blockers should not be administered concurrently. Levosalbutamol should be used with caution in patients receiving other sympathomimetic.

Levosalbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of these agents, since the action of Levosalbutamol on the vascular system may be potentiated.

Soventus®-LS Syrup with food and drink

It is recommended to take Soventus®-LS Syrup with food.

Use in Special Population:

Pregnancy

Since there are no adequate and well-controlled studies of this combination in pregnant women, this medicine should be administered with caution.

Lactation

Levosalbutamol is secreted into breast milk, but any effect on the infant is unlikely at therapeutic doses. Transient hypoglycaemia has been reported in new-born preterm infants after maternal β -2 agonist treatment. Since Guaifenesin is excreted in breast milk in small amounts, decision must be made to continue with the medicine if benefit of drug outweighs the risks of treatment.

Geriatric Population

They are more sensitive to the effects of Levosalbutamol; hence a lower dose may be required.

Pediatric population

Not recommended for children below 2 years of age.

Hepatic & Renal Insufficiency

Caution should be exercised in patients with moderate to severe renal impairment and liver disease.

Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Soventus syrup is known.

3. How to take Soventus®-LS Syrup

Always take Soventus syrup exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- If you feel that this medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

Children between 2 to 6 years: 2.5 ml to be administered 3 times daily.

Children between 6 to 12 years: 5 ml to be administered 3 times daily.

Adults and children above 12 years: 10 ml to be administered 3 times daily.

If you take more Soventus®-LS Syrup than you should

If you take more Soventus syrup than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Soventus®-LS Syrup

If you forget a dose, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

4. Possible Side Effects

The most common adverse reactions with Ambroxol are nausea, oral and pharyngeal hypoesthesia, dyspepsia, dry mouth, abdominal pain and allergic reactions such as skin rash or urticaria can also occur.

Tremor and headache are the most common adverse events observed with Levosalbutamol administration. Tachycardia, palpitations, muscle spasms and hypokalaemia are few other common adverse reactions observed.

Guaifenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, particularly in very high doses. Allergic reactions, angioedema, anaphylactic reactions, dyspnoea (reported in association with other symptoms of hypersensitivity), nausea, vomiting, abdominal discomfort, rash and urticaria may also occur.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “**Safety Reporting**” located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Soventus®-LS Syrup

- Store below 25⁰C, protected from light & moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Keep away from the reach of children. Do not freeze.

6. Contents of the pack and other information

What Soventus®-LS Syrup contains:

Each 5 ml Contains:

Levosalbutamol sulphate

equivalent to levosalbutamol IP.....1 mg

Ambroxol Hydrochloride IP.....30 mg

Guaiphenesin IP.....50 mg

Excipients q. s.

1x100ml, PET Bottle

- **Marketing Authorisation Holder**

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This leaflet was last revised in 10/2023.