

Soventus[®] Syrup

(Ambroxol Hydrochloride, Terbutaline Sulphate, Guaifenesin & Menthol 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[®] Syrup is and what it is used for
2. What you need to know before you take Soventus[®] Syrup
3. How to take Soventus[®] Syrup
4. Possible side effects
5. How to store Soventus[®] Syrup
6. Contents of the pack and other Information

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

Soventus[®] Syrup is the combination of Ambroxol Hydrochloride, Terbutaline Sulphate, Guaifenesin & Menthol 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. **Terbutaline sulphate** is used as a bronchodilator. It causes bronchodilation, 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. **Menthol** is an alcohol produced from mint oils and carries flavouring and local

anaesthetic properties. It also has a counterirritant effect on skin and mucous membranes, thereby producing a local analgesic or anaesthetic effect. One of the major effects of menthol when applied to the skin or a mucosal surface is to cause a sensation of coolness; this was attributed to stimulation of thermos-receptors present on the sensory nerves.

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

Do not take Soventus® 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 Terbutaline, caution should be observed in patients with thyrotoxicosis. Cardiovascular effects may be seen with sympathomimetic drugs, including terbutaline.

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.

Menthol should not be used in consistent and chronic cough with excessive mucin secretions.

Other medicines and Soventus® 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.

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

Terbutaline 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 terbutaline on the vascular system may be potentiated.

The concomitant use of menthol cough syrup with warfarin may reduce the therapeutic effects of warfarin. Large doses of menthol may affect the felodipine metabolism by inhibiting CYP3A4.

Soventus® Syrup with food and drink

Fasting bioavailability after oral doses is reported to be about 14 to 15% and is reduced by 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

Terbutaline is secreted into breast milk, but any effect on the infant is unlikely at therapeutic doses. Transient hypoglycaemia has been reported in newborn 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. It is preferable to avoid use of menthol based cough syrups during pregnancy or lactation.

Geriatric Population

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

Pediatric population

Not recommended for children below 6 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 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

Adults (12 years & above): 10 ml (2 teaspoonful) 3 times a day.

Children (6-12 years): 5 - 10 (1 - 2 teaspoonful) 3 times a day.

If you take more Soventus 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 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 Terbutaline 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.

Possible side effects from the use of high doses of Menthol are allergic reactions, facial swelling, throat disorder, nausea, vomiting, vertigo, ataxia, drowsiness, exhaustion and stomach pain.

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 Syrup

- Store below 25°C, 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 Syrup contains

Each 5 ml Contains:

Ambroxol Hydrochloride IP....20 mg

Terbutaline Sulphate IP.....1.25 mg

Guaifenesin IP.....50 mg

Menthol IP.....0.5 mg

Excipients q. s.

Colour Tartrazine Supra

In a flavoured syrup base

1x100ml, PET Bottle

- **Marketing Authorisation Holder**
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This leaflet was last revised in 10/2023.