Soventus® Jr. Syrup

(Ambroxol Hydrochloride, Terbutaline Sulphate & Guaiphenesin Syrup)

Read all of this leaflet carefully before your child starts 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, please ask your child's doctor, pharmacist or nurse.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- The full name of this medicine is Ambroxol Hydrochloride, Terbutaline Sulfate, & Guaiphenesin Syrup but within the leaflet it will be referred to as Soventus Jr syrup.

What is in this leaflet:

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

2. What you need to know before your child takes Soventus® Jr. Syrup

3. How to take Soventus® Jr. Syrup

4. Possible side effects

5. How to store Soventus® Jr. Syrup

6. Contents of the pack and other Information

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

Soventus Jr Syrup is a combination of Terbutaline sulphate, ambroxol hydrochloride and Guaiphenesin.

Terbutaline is a selective beta 2 -adrenergic agonist which predominantly stimulates beta 2-receptors, thus producing relaxation of bronchial smooth muscle. Ambroxol possesses mucokinetic (improvement in mucus transport) and secretolytic (liquifies secretions) properties. It promotes the removal of tenacious secretions in the respiratory tract and reduces mucus stasis (arresting the secretion of mucus). Besides that, Ambroxol also exhibits anti-oxidant activity. Guaiphenesin, by increasing respiratory tract fluid, reduces the viscosity of tenacious secretions and acts as an expectorant. Another possible mechanism by which it acts is by increasing the water bonding in the sputum, thereby decreasing its viscosity and leading to an increase in mucokinesis. Guaiphenesin is effective in both productive and non-productive coughs.

Soventus Jr syrup is used for the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis.

Your child's doctor will determine how Soventus Jr syrup should be used depending on the symptoms and severity of your child's disease.

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

Do not take Soventus Jr syrup if your child is:

- 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

Talk to your child's doctor, pharmacist or nurse before using Soventus® Jr. Syrup

Terbutaline

As for all beta 2-agonists caution should be observed in patients with thyrotoxicosis.

Cardiovascular effects may be seen with sympathomimetic drugs, including terbutaline. There is some evidence from post-marketing data and published literature of myocardial ischaemia associated with beta agonists. Terbutaline, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of terbutaline at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiogram (ECG) changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Therefore, terbutaline, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Due to the positive inotropic effect of beta 2-agonists, these drugs should not be used in patients with hypertrophic cardiomyopathy. Terbutaline, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, including ischemic heart disease, hypertension, and cardiac arrhythmias; hyperthyroidism; diabetes mellitus; hypersensitivity to sympathomimetic amines; and convulsive disorders. Significant changes in systolic and diastolic blood pressure have been seen and could be expected to occur in some patients after use of any beta-adrenergic bronchodilator.

Beta-adrenergic agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.

Large doses of intravenous terbutaline have been reported to aggravate pre-existing diabetes and ketoacidosis.

Respiratory indications

Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving Terbutaline should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease.

Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Due to the hyperglycaemic effects of beta 2-agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalaemia may result from beta 2-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalaemic effect may be potentiated by concomitant treatments. It is recommended that serum potassium levels are monitored in such situations.

If a previously effective dosage regimen no longer gives the same symptomatic relief, the patient should urgently seek further medical advice. Consideration should be given to the requirements for additional therapy (including increased dosages of anti-inflammatory medication). Severe exacerbations of asthma should be treated as an emergency in the usual manner.

There have been rare reports of seizures in patients receiving terbutaline; seizures did not recur in these patients after the drug was discontinued.

Ambroxol

Care to be taken to avoid contact with eye, skin, serious ingestion or inhalation.

Guaiphenesin

Guaiphenesin should be not used for persistent or chronic cough, or where cough is accompanied by excessive secretions, unless directed by a physician. A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

Caution should be exercised in the presence of severe renal or severe hepatic impairment. The concomitant use of cough suppressants is not recommended.

Patients with rare hereditary problems of fructose intolerance should not take this medicine. Not more than 4 doses should be given in any 24 hours. Avoid with any other cough and cold medicine.

Consult a healthcare professional before use in children under 6 years. Stop use and ask a healthcare professional if your cough lasts for more than 7 days, comes back, or is accompanied

by a fever, rash, or persistent headache. Do not take with a cough suppressant. Do not give this medicine with any other cough or cold medicines.

Other medicines and Soventus Jr syrup

Terbutaline

Beta-blocking agents (including eye drops); especially the non-selective ones such as propranolol, may partially or totally inhibit the effect of beta-stimulants. Therefore, terbutaline preparations and non-selective beta-blockers should not normally be administered concurrently. Terbutaline should be used with caution in patients receiving other sympathomimetics.

Potassium depleting agents and hypokalaemia

Owing to the hypokalaemic effect of beta-agonists, concurrent administration with terbutaline of serum potassium depleting agents known to exacerbate the risk of hypokalaemia, such as diuretics, methyl xanthines and corticosteroids, should be administered cautiously after careful evaluation of the benefits and risks with special regard to the increased risk of cardiac arrhythmias arising as a result of hypokalaemia. Hypokalaemia also predisposes to digoxin toxicity. Hypokalaemia may result from beta 2-agonist therapy and may be potentiated by concomitant treatment with xanthine derivatives, corticosteroids and diuretics.

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 such agents, since the action of terbutaline on the vascular system may be potentiated.

Ambroxol

No data available

Guaiphenesin

If urine is collected within 24 hours of a dose of Guaiphenesin, its metabolite may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Others

Soventus Jr. Syrup should be used with caution in patients with diabetes mellitus, serious cardiovascular disorders, hypertension, hyperthyroidism and peptic ulcers.

USE IN SPECIAL POPULATION:

Pregnancy

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

Lactation

It is not known whether this combination is secreted in breast milk. However, terbutaline is secreted in breast milk, but effect on the infant is unlikely at therapeutic doses. Therefore, this combination should be used with caution in nursing mothers.

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 Jr syrup is known.

3. HOW TO TAKE SOVENTUS JR SYRUP

- Always use this medicine exactly as your child's doctor has told you. Check with your child's doctor or pharmacist if you are not sure.
- This medicine is to be given to a child under adult supervision.
- It should be taken even when your child has no symptoms.
- To be taken by mouth

How much to take

Children (under 6 years) 5 - 10 ml thrice daily

Children (6-12 years) 10 ml thrice daily

Always take the product exactly as advised. You should check with your doctor or pharmacist if you are not sure. Only to be taken by mouth. Shake the bottle well before measuring the dose in the measuring cap provided with bottle.

If you take more Soventus Jr syrup than you should

Contact your child's doctor immediately for advice. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Soventus Jr syrup

Try to give Soventus Jr syrup as prescribed. However, if your child misses a dose, just resume the usual schedule. Do not give a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Ambroxol Hydrochloride

Under individual hypersensitivity to Ambroxol allergic reactions such as skin rash, nettle-rash, and angioneurotic oedema are possible. Under the prolonged administration in large doses pain in epigastric area, nausea, vomiting can appear.

Gastrointestinal Disorders: Dyspepsia, nausea, vomiting, diarrhoea and abdominal pain.
Respiratory Disorders: Oral and pharyngeal hypoaesthesia, dry mouth and dry throat.
Nervous System Disorders: dysgeusia (e.g., changed taste).
Immune System Disorders: Anaphylactic reactions including anaphylactic shock.

Skin and Subcutaneous Tissue Disorders: Angioedema, rash, urticaria, pruritus and other hypersensitivity.

Terbutaline Sulphate

Most of the adverse reactions are characteristic of sympathomimetic amines. The majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment. The frequency of side-effects is low at the recommended doses.
The common adverse reactions to terbutaline are tremor, headache, tachycardia, palpitations, muscle spasms and hypokalaemia, nervousness, somnolence, dizziness, anxiety, insomnia, extra systoles ventricular, vasodilations, nausea, dry mouth, asthenia, sweating.
The following adverse effects each occurred in fewer than 1% of patients: hallucinations, rash, paraesthesia, hypertonia, (muscle cramps), vomiting.
There have been rare reports of elevation in liver enzymes and of hypersensitivity vasculitis.
Rare cases of arrhythmias e.g. atrial fibrillation, supraventricular tachycardia and extra systoles, myocardial ischaemia, peripheral vasodilation, hypersensitivity reactions including angioedema, bronchospasm, hypotension, collapse, nausea, mouth and throat irritation, sleep disorder, behavioural disturbances such as agitation and restlessness, paradoxical bronchospasm, urticaria and rash.

Guaiphenesin

Side effects resulting from Guaiphenesin administration are very rare. Guaiphenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, gastrointestinal discomfort particularly in very high doses. Also, hypersensitivity reactions may occur. The frequency of these Guaiphenesin-related adverse reactions is unknown but based on estimate from post-marketing data are likely to be rare: Allergic reactions, angioedema, anaphylactic reactions, dyspnoea, nausea, vomiting, abdominal discomfort, rash, urticaria.

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 JR SYRUP

- Store protected from light & moisture. Store below 25^0C. Shake well before use.
- 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.

6. Contents of the pack and other information

What Soventus Jr syrup contains

Each 5 ml contains:
Ambroxol Hydrochloride…. 10 mg

Terbutaline Sulphate…….. 0.5 mg
Guaiphenesin IP…… 25 mg
Excipients (q.s.)

A bottle of 60 ml.

Marketing Authorisation Holder

Zuventus Healthcare Limited

Zuventus House, Plot Y2, CTS No.: 358/A2,

Near Nahur Railway Station,

Nahur (W), Mumbai, 400078 Maharashtra, India.

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