VENTOLIN™ SYRUP

Salbutamol

QUALITATIVE AND QUANTITATIVE COMPOSITION

VENTOLIN Syrup contains 2mg salbutamol BP, as sulphate, in each 5ml of syrup.

PHARMACEUTICAL FORM

Syrup.

CLINICAL PARTICULARS

Indications

Symptomatic treatment of asthma and other reversible obstructive pulmonary diseases in children and babies.

Note : the administration of salbutamol in syrup form must be envisaged only in situations where another bronchodilator-based medicinal product appropriate to the clinical situation cannot be used. This medicinal product should not be used to treat an asthma attack. In the event of an attack, depending on the gravity, an inhaled or injectable short-acting rescue bronchodilator must be used.

Dosage and Administration

Posology

One 2.5 ml measuring spoon of syrup contains 1 mg of salbutamol.
One 5 ml measuring spoon contains 2 mg of salbutamol.

- **Children**

The daily dose for babies and children will not usually exceed: 0.20 to 0.30 mg/kg/day.
i.e. as a guide:
from 1 month - 2 years: 2.5 ml (1 milligram salbutamol) 2 to 3 times daily.
2-6 years 2.5-5ml of syrup (1-2 milligram salbutamol) three or four times daily.
6-12 years 5ml to 10 ml (2-4 milligram salbutamol) three or four times daily.
Method of administration
Oral.

Contraindications

VENTOLIN Syrup is contraindicated in patients with a history of hypersensitivity to any of its components.

Although intravenous VENTOLIN and occasionally VENTOLIN tablets ***and*** VENTOLIN **suppositories** are used in the management of premature labour, uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy, VENTOLIN presentations should not be used for threatened abortion.

Warnings and Precautions

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled β2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.
Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

VENTOLIN should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from β2 agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

In common with other β-adrenoceptor agonists, VENTOLIN can induce reversible metabolic changes, for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Long term treatment with VENTOLIN Syrup (Sugar-containing formulation) increases the risk of dental caries. It is important that adequate dental hygiene is maintained.

Interactions

VENTOLIN and non-selective β-blocking drugs, such as propranolol, should not usually be prescribed together.
VENTOLIN is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

Pregnancy and Lactation

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the offspring of patients being treated with salbutamol. Some of the mothers were taking multiple medications during their pregnancies. Because no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2-3%, a relationship with salbutamol use cannot be established.

As salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

Adverse Reactions

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

Immune system disorders

Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.

Metabolism and nutrition disorders
Rare: Hypokalaemia.

Potentially serious hypokalaemia may result from beta2 agonist therapy.

Nervous system disorders
Very common: Tremor.
Common: Headache.
Very rare: Hyperactivity.

Cardiac disorders
Common: Tachycardia, palpitations.
Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorders
Rare: Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders
Common: Muscle cramps.
Very rare: Feeling of muscle tension.

Overdose
Symptoms and Signs
The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events (see Warnings and Precautions and Adverse Reactions).
Hypokalaemia may occur following overdose with VENTOLIN. Serum potassium levels should be monitored.
Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

Treatment
Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy such as cardio-selective beta-blocking agents in patients presenting with cardiac symptoms (e.g. tachycardia, palpitations). Beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

PHARMACEUTICAL PARTICULARS
List of Excipients
Saccharin sodium, Citric acid monohydrate, Sodium citrate dihydrate, Hypromellose (4000), Sodium benzoate, Sodium chloride, Orange flavour*, Purified water
* Composition of orange flavour: alpha-pinene, myrcene, limonene, decanal, linalol in solution in propylene glycol and isopropyl alcohol.

Incompatibilities
Dilution of VENTOLIN Syrup with Syrup BP or Sorbitol solution is not recommended as this may result in precipitation of the cellulose thickening agent.

Shelf Life
The expiry date is indicated on the packaging.

Special Precautions for Storage
Purified Water BP may be used as diluent but the resulting mixture will keep only 28 days at 30°C.
Do not store above 30°C.
Protect from light.

Instructions for Use/Handling
Dilution:
VENTOLIN Syrup may be diluted with Purified Water BP (50% v/v). The resulting mixture should be protected from light and used within 28 days.
A 50% v/v dilution of VENTOLIN Syrup has been shown to be adequately preserved against microbial contamination. However, to avoid the possibility of introducing excessive microbial contamination, the Purified Water used for dilution should be recently prepared or alternatively it should be boiled and cooled immediately before use.
Admixture of VENTOLIN Syrup with other liquid preparation is not recommended.

Manufactured by:
Farmaclair,
Hérouville-Saint-Clair, France

Version number: GDS20/IPI04
Date of issue: 24 June 2008

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

gsk GlaxoSmithKline