ZENMOLIN SYRUP 2MG/5ML

COMPOSITION:

Each 5ml contains: Salbutamol Sulphate BP equivalent to Salbutamol 2mg
Preservative: Sodium Benzoate 0.1%w/v.

Excipients: Sodium Carboxymethylcellulose, Sodium Citrate Dihydrate, Citric Acid Monohydrate, Sodium Saccharin, Cherry oil H2367, Purified Water.

PROPERTIES:

ZENMOLIN contains salbutamol, which is a direct-acting sympathomimetic agent with selective action on beta 2 receptors. Its bronchodilating action is more prominent than its effect on the heart. Hence it is used as a bronchodilator.

INDICATIONS:

For the relief and prevention of bronchospasm in bronchial asthma, in chronic bronchitis, and in emphysema.

Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to ZENMOLIN, treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with ZENMOLIN may signal a need for urgent medical advice or treatment.

RECOMMENDED DOSAGE: Orally

Adults : 10 - 20 ml (5ml for elderly and sensitive patients)
Children : 2 - 5 yrs : 2.5 - 5ml
6 - 12 yrs : 5ml
Over 12 years: 5-10 ml

Doses to be given 3 - 4 times daily.

Special patient groups:

In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 2 mg (5ml) salbutamol 3 or 4 times per day.

Contraindications

Salbutamol syrup is contraindicated in patients with a history of hypersensitivity to any of its components.
Non-i.v. formulations of Salbutamol must not be used to arrest uncomplicated premature labour or 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 beta-$_2$ 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 is reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from beta-$_2$ 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 beta-adrenoceptors agonists, Salbutamol 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 ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Salbutamol syrup is not indicated for obstetric use.

Interactions

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

Pregnancy and Lactation

Pregnancy

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.

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As no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2- to 3%, a relationship with salbutamol use cannot be established.

Lactation
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 reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions 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 beta-2 agonist therapy.

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

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

Cardiac disorders
Common: Tachycardia, palpitations.
Uncommon: Myocardial ischaemia*
*In the management of pre-term labour with Ventolin injection/solution for infusion.
Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorder
Rare: Peripheral vasodilatation.

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

Overdose
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 Salbutamol. Serum potassium levels should be monitored.
Lactic acidosis has been reported very rarely in association with high therapeutic doses of intravenous and nebulised short-acting beta-agonist therapy, mainly in patients being treated for an acute asthma exacerbation (see Adverse Reaction section). Increase in lactate levels may lead to dyspnoea and compensatory hyperventilation, which could be misinterpreted as a sign of asthma treatment failure and lead to inappropriate intensification of short-acting beta-agonist treatment. It is therefore recommended that patients are monitored for the development of elevated serum lactate and consequent metabolic acidosis in this setting.
Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when Salbutamol overdose has been taken via the oral route.

Treatment
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

STORAGE:
Store below 30°C in a dry place and protect from light.

AVAILABILITY:
3.8 litres in plastic container
100 ml in amber glass bottle
Not all presentations may be available locally.

DATE OF REVISION: September 2022

For further information, please consult your physician or pharmacist.

Manufactured by:
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