ASMOL SYRUP 2MG/5ML

Each 5ml contains:

Salbutamol sulphate equivalent to Salbutamol	2mg

Product Description:
A clear, colourless syrup with cherry flavour.

Pharmacodynamics:
Salbutamol exerts a direct effect on β_2 receptors including those of the bronchial tree and uterus. It is a selective β_2 receptor stimulant. Its bronchodilating effect is relatively more prominent than the effect on the heart. Salbutamol stimulates β-adrenergic receptors and has little or no effect on β_1-adrenergic receptors. It is believed that β-adrenergic agonists stimulate the production of cyclic adenosine -3", 5"- monophosphate (AMP) by activation of the enzyme adenylyl cyclase. Cyclic AMP appears to mediate numerous cellular responses. Salbutamol appears to have a greater stimulating effect on β-adrenergic receptors of the bronchial, uterine, vascular smooth muscles (β_2 receptors) than on β-adrenergic receptors of the heart (β_1 receptors). The main effect following oral inhalation or oral administration of salbutamol is bronchodilation resulting from relaxation of smooth muscles of the bronchial tree; the drug also has some vasodilating effect on peripheral vasculature and may decrease diastolic blood pressure to a small extent. In patients with reversible airway obstruction, salbutamol decreases resistance of the airways as measured by pulmonary function tests such as the forced expiratory volume in 1 second (FEV 1) and the maximum mid - expiratory flow rate; the drug also increases vital capacity. Although the clinical importance has not been established, tolerance to the bronchodilating effects of salbutamol has been reported in healthy individuals and in patients with asthma. In contrast to isoproterenol, salbutamol does not appear to decrease arterial oxygen tension. Salbutamol may cause reflex tachycardia, especially with higher than usual doses.

Pharmacokinetics:
Salbutamol is readily absorbed from the gastro-intestinal tract. It is subjected to first- pass metabolism in the liver and possibly in the gut wall; about half is excreted in the urine as an inactive sulphate conjugate, following oral administration (the rest being unchanged salbutamol). Whereas less is excreted as the conjugate following intravenous administration. Salbutamol does not appear to be metabolised in the lung, therefore its ultimate metabolism and excretion following inhalation depends upon the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. The plasma half-life of salbutamol has been estimated to range from about 2 to as much as 7 hours.

Indication:
It is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease.

Recommended Dosage:
The dosages are expressed in terms of salbutamol base.
Usual Dosage
The usual starting dosage for adults and children 12 years and over is 2mg (5ml) or 4mg (10ml) three or four times a day.
Dosage Adjustment
Doses above 4mg (10ml), four times a day should be used only when the patients fail to respond. If a favourable response does not occur with the 4mg (10ml) initial dosage, it should be cautiously increased stepwise up to a maximum of 8mg (20ml) four times a day as tolerated. The total daily dose should not exceed 32mg (80ml) in adults and children 12 years and over. The usual starting dose for children 6 to 12 years in age is 2mg (5ml) three or four times a day. For children from 6 to 12 years who fail to respond to initial starting dosage of 2mg (5ml) four times a day, the dosage may be cautiously increased stepwise but not to exceed 24mg (60ml) per day (in divided doses).

Route of Administration: Oral

Contraindications:
It is contraindicated in patients with a history of hypersensitivity to it. Although intravenous salbutamol and occasionally salbutamol tablets are used in the management of premature labour, uncomplicated by conditions such as placenta previa, antepartum haemorrhage or toxaemia of pregnancy, salbutamol presentations should not be used for threatened abortion during the first or second trimester of pregnancy.

Warnings and Precautions:
Tocolysis: Serious adverse reaction including death have been reported after administration of terbutaline/ salbutamol to women in labor. In the mother, these include increased heart rate, transient hyperglycaemia, hypokalaemia, cardiac arrhythmias, pulmonary oedema and myocardial ischaemia. Increased fetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration. Although salbutamol usually has minimal effect on the β_1-receptor of the cardiovascular system at the recommended dosage, occasionally the usual cardiovascular and CNS stimulatory effects common to all sympathomimetic agents have been reported. Therefore, salbutamol should be used with caution in patients with cardiovascular disorders, including coronary insufficiency and hypertension, in patients with hyperthyroidism or diabetes mellitus, and in patients who are unusually responsive to sympathomimetic amines. The action of salbutamol may last for six hours or longer and therefore it should not be taken more frequently than recommended. Salbutamol should be used with caution in patients with suspected or diagnosed pheochromocytoma. In patients with hyperkalemic familial periodic paralysis, salbutamol may decrease serum potassium concentration by stimulating the intercellular transport of potassium.

Interactions with Other Medicaments:
The concomitant use of salbutamol and other oral sympathomimetic agents is not recommended since such combined use may lead to deleterious cardiovascular effects. Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic anti-depressants, since the action of salbutamol on the vascular system may be potentiated. β-receptors blocking agents and salbutamol inhibit the effects of each other. Administration of high doses of salbutamol prior to or shortly after anaesthesia with chloroform, halothane, cyclopropane or trichloroethylene may increase the risk of severe ventricular arrhythmias, especially in patients with pre-existing heart disease, because these anaesthetics greatly sensitize the myocardium to the effects of sympathomimetic.

Pregnancy and Lactation:
There is no adequate and well-controlled studies for the use of salbutamol in pregnant and nursing mother. It is not known if salbutamol is distributed into milk. Hence, salbutamol should be used in pregnant and lactating women only if the benefits clearly outweigh the risks.

Side Effects:
The most frequent side effects of salbutamol are nervousness and tremor, headache, tachycardia and palpitations, muscle cramps, insomnia, nausea, weakness and dizziness. Drowsiness, flushing, restlessness, irritability, chest discomfort and difficulty in micturition have also been reported. In addition, salbutamol, like other sympathomimetic agents, can cause adverse reactions such as hypertension, angina, vomiting, vertigo, central stimulation, unusual taste and drying or irritation of the oropharynx.

Symptoms and Treatment of Overdose:
Manifestations of overdosage include angina pain, hypertension, hypokalemia and exaggeration of the effects listed in 'Side Effects'. Most adverse effects subside rapidly when treatment is stopped. The judicious use of a cardioselective β-receptor blocker, such as metoprolol tartrate, is suggested bearing in mind the danger of inducing an asthmatic attack.

Effects on Ability to Drive and Use Machine: None known.

Storage Conditions: Store at or below 30°C. Protect from light.

Pack Sizes: A bottle of 60ml, 100ml and 120ml.
Pack Sizes (export only): A bottle of 3.6 litres and 3.8 litres.

Shelf life: 3 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:
Sunward Pharmaceutical Sdn. Bhd.
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81200 Johor Bahru, Johor, Malaysia.

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