SALTOLINE SYRUP

MAL19910172AZ

DESCRIPTION:
SYRUP
Colour : Red
Flavour : Strawberry

CONTENT:
Each 5 ml contains:
Salbutamol Sulphate equivalent to Salbutamol ..... 2 mg
Preservatives: Methyl Paraben 0.2% w/v & Propyl Paraben 0.02% w/v.

PHARMACODYNAMICS:
Salbutamol is a directly acting sympathomimetic amine. Its main action is on the adrenoceptors in the bronchi and the respiratory tract rather than on the cardiac receptor. For this reason it induces bronchodilatation and inhibits bronchospasms in doses which do not produce marked cardiac acceleration.

PHARMACOKINETICS:
Salbutamol is rapidly absorbed after oral administration. After an oral dose of 4 to 8 mg, peak plasma concentrations of about 23 ng/ml for unchanged drug and 50 to 100 ng/ml for unchanged drug plus metabolite are attained in 2.5 to 3 hours. Plasma half-life is 2 to 7 hours. Salbutamol is metabolised by first pass metabolism, the reactions and metabolites involved are not yet identified. About 75 to 95% of an oral dose is excreted in the urine and about 4% in the faeces in 3 days. Following oral administration, 50 to 60% of the urinary excreted material is metabolised.

INDICATION:
It is used in the relief of asthma, chronic bronchitis, emphysema and other bronchopulmonary disorders involving bronchospasm.

RECOMMENDED DOSE:

Adults	:	Oral, 1 to 3 teaspoonfuls (5 to 15 ml) 3 to 4 times a day initially, the dosage being increased as needed and tolerated up to a maximum of 4 teaspoonfuls (20 ml) 4 times a day.	
Children	:	**Less than 2 years**	: Dosage has not been established.
		2-6 years	: 100 mcg/kg body weight, 3 times a day initially. The dosage being increased as needed and tolerated up to 200 mcg/kg body weight not to exceed 4 mg 3 times a day.
		6-14 years	: 1 teaspoonful (5 ml) 3 to 4 times a day initially, the dosage being increased as needed and tolerated up to a maximum of 12 teaspoonfuls (60 ml)/day in divided doses.
		More than 14 years	: Usual adult dose.

ROUTE OF ADMINISTRATION:
FOR ORAL USE ONLY

CONTRAINDICATIONS:
It is contraindicated in patients with hypertension, myocardial insufficiency and hyperthyroidism.

WARNINGS AND PRECAUTIONS:
Safety and efficacy of Salbutamol oral solution has not been established in children younger than 2 years of age.
Tocolysis: Serious adverse reactions including death have been reported after administration of 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.

DRUG INTERACTIONS:
Salbutamol should not be administered with non-selective beta-adrenoceptor blocking drugs such as Propranolol or Oxprenolol.

PREGNANCY AND LACTATION:
Risk and benefit should be considered when used during pregnancy. Safe use of the drug in pregnant women has not been established. It is not known whether Salbutamol is distributed into milk. Therefore a decision should be made whether to discontinue nursing or Salbutamol, taking into accounts the importance of the drug to the women.

SIDE EFFECTS:
Palpitation, tachycardia and muscle tremors may occur. Peripheral vasodilatation, tremor, nervousness, nausea, vertigo, central stimulation, hyperactivity, excitement, irritable behaviour, insomnia, epitaxis, weakness, dizziness, unusual taste, heartburn, drowsiness, difficulty in micturition, cough and drying irritation of the oropharynx, anorexia, emotional lability, pallor, fatigue, conjunctivitis, muscle cramps and headaches.

SYMPTOMS AND TREATMENT OF OVERDOSE
Symptoms of overdose include muscle tremors, flushing, agitation, palpitations, sinus tachycardia and hypokalemia. Treatment includes gastric lavage or emesis and the use of beta-adrenoceptor blocking agents, usually Propranolol.

PACKING/PACK SIZE(S):
Plastic bottle of 60 ml.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN
SHAKE WELL BEFORE USE

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)
2497, Mk. 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3,
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