100mm

150mm

REXOM™ SALBUTAMOL ELIXIR 2MG/5ML

Name and Strength of Active Ingredient(s)
Each 5 ml contains :
Salbutamol Sulphate BP equivalent to
Salbutamol BP ..... 2 mg
Preservative :
Sodium Benzoate ..... 0.2% w/v

Product Description
Pink colour liquid with strawberry flavour.

Pharmacodynamics
Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses, it works on the beta-2 adrenoceptors of bronchial muscle.

Pharmacokinetics
Salbutamol is absorbed from the gastrointestinal tract after oral administration and the bioavailability of orally administered salbutamol is about 50%. Both unchanged drug and conjugate are excreted primarily in the urine.

Indications
Salbutamol is used as a bronchodilator in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease.

Recommended Dose
2 to 6 years: 2.5 ml to 5 ml, 3 times a day.
6 to 12 years: 5 ml, 3 times a day.
Over 12 years: 5 ml to 7.5 ml, 3 times a day.
Over 65 years and sensitive patients: 5 ml, 3 times a day.

Route of Administration
Oral

Contraindications
Salbutamol Elixir is contra-indicated in patients with a history of hypersensitivity to any of their components.

Warnings and Precautions
Salbutamol Elixir should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension and diabetes mellitus. In severe asthma particular caution is also required to avoid inducing hypokalaemia as this effect may be potentiated by hypoxia or by concomitant use of other anti-asthma drugs.
Tocolysis: Serious adverse reactions 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.

Interactions With Other Medicaments
Use of Salbutamol Elixir with corticosteroids, diuretics or xanthines increases the risk of hypokalaemia and monitoring of potassium concentrations is recommended in severe asthma.

Pregnancy and Lactation
Administration of this drug during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.
There is little published evidence of its safety in the early stages of human pregnancy, but in animal studies, there was evidence of some harmful effects on the foetus at very high dose levels.
Its use in nursing mother is not recommended as salbutamol is probably secreted in breast milk unless the expected benefit to the mother is likely to outweigh any potential risk to the neonate. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

Side Effects
Salbutamol, like other beta agonists, may cause fine tremor of skeletal muscle (particularly the hands), palpitations, tachycardia, nervous tension, headaches, peripheral vasodilatation and rarely muscle cramps.

Overdose and Treatment
Reports of overdosage with salbutamol that may be expected are tachycardia, CNS stimulation, tremor, hypokalaemia and hyperglycaemia. Symptomatic treatment of the adverse effects has proved successful.

Storage Conditions
Keep container tightly closed. Store below 30°C. Protect from heat and light.
Keep out of reach of children. Jauhi dari kanak-kanak.

Dosage Forms
Oral liquid

Pack Size
60ml and 100ml.

Registration Number
MAL19900151AZ

Manufactured by & Product Registration Holder
KCK PHARMACEUTICAL INDUSTRIES SDN. BHD.
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