PRODUCT INSERT PRINTED ON INSIDE PANEL OF THE BOX

SALBUTAMOL

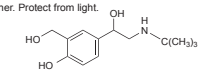
2 mg/5 mL Syrup

Bronchodilator

SALBUTAMOL 2 mg/5 mL Syrup **Bronchodilator** ℞

FORMULATION
Each 5 mL (1 teaspoonful) contains:
SALBUTAMOL (as sulfate) ..... 2 mg
(Equivalent to 2.41 mg Salbutamol as sulfate)

DESCRIPTION
A white or practically white powder. Freely soluble in water; slightly soluble in alcohol, in chloroform, and in ether. Protect from light.



PRODUCT DESCRIPTION
Clear pink syrup with sweet strawberry taste containing 2 mg of Salbutamol in each 5 mL.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Salbutamol is a direct-acting sympathomimetic with mainly beta-adrenergic activity and a selective action on beta2 receptors. This results in its bronchodilating action being more prominent than its effect on the heart. Salbutamol and salbutamol sulfate are used as bronchodilators in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease. Salbutamol also decreases uterine contractility and may be given as the sulfate to arrest premature labour.

Pharmacokinetics
Salbutamol is readily absorbed from the gastrointestinal tract. When given by inhalation, 10 to 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is swallowed and absorbed from the gut. Salbutamol is subject to first-pass metabolism in the liver and possibly in the gut wall but does not appear to be metabolised in the lung; the main metabolite is the inactive sulfate conjugate. Salbutamol is rapidly excreted, mainly in the urine, as metabolites and unchanged drug; a smaller proportion is excreted in the faeces. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

DRUG INTERACTION
Use of salbutamol and other beta2 agonists with corticosteroids, diuretics, or xanthines increases the risk of hypokalaemia, and monitoring of potassium concentrations is recommended in severe asthma, where such combination therapy is common.

INDICATIONS
For the treatment and prevention of bronchospasms in bronchial asthma, bronchitis, and acute dyspnea, routine maintenance in chronic asthma and bronchitis.

DOSAGE AND MODE OF ADMINISTRATION
Adults: One (1) to two (2) teaspoonfuls (5-10 mL)
Children:
6-12 years old: One (1) teaspoonful (5 mL)
2-5 years old: One-half (½) to one (1) teaspoonful (2.5 mL-5 mL)
To be taken orally, three (3) to four (4) times a day.
Or as prescribed by a physician.

CONTRAINDICATION
Salbutamol syrup is contra-indicated in patients with a history of hypersensitivity to any of its components.

ADVERSE REACTIONS
Salbutamol has mainly beta-agonist effects and, 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. Inhalation causes fewer adverse effects than systemic dosage, and the more selective beta-2 agonists cause fewer adverse effects than less selective beta agonists. Potentially serious hypokalaemia has been reported after large doses. Myocardial ischaemia has also been reported. Hypersensitivity reactions have occurred, including paradoxical bronchospasm, angioedema, urticaria, hypotension, and collapse. The high doses of salbutamol used intravenously to delay premature labour have additionally been associated with nausea and vomiting, and with severe adverse cardiac and metabolic effects and pulmonary oedema.

PREGNANCY AND LACTATION
Most adverse effects associated with salbutamol in pregnancy relate to the cardiovascular and metabolic effects of the very high doses given by intravenous infusion in attempts to delay premature labour. Maternal effects include myocardial ischaemia, unifocal ventricular ectopics associated with the hypokalaemic response to intravenous salbutamol, and heart failure in a hypertensive woman. Similarly, serious fetal and neonatal cardiovascular complications have also been associated with tocolytic salbutamol. Metabolic acidosis after salbutamol infusions in diabetic women has also been reported.

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.

OVERDOSE AND TREATMENT
Reports of overdosage with salbutamol have generally only described the features that may be expected with beta-2 agonists such as tachycardia, CNS stimulation, tremor, hypokalaemia, and hyperglycaemia. Symptomatic treatment of the adverse effects has proved successful although it is unlikely to be required after repeated inhalation. Activated charcoal may be considered after oral overdose in patients who have taken a potentially toxic amount and present within 1 hour. The plasma potassium concentration and pulse rate have been found to correlate with the plasma concentration of salbutamol.

PRECAUTIONS
Should not be used for threatened abortion during the first and second trimester. Salbutamol oral preparation and beta blocking drugs should not usually be prescribed together.

ADR REPORTING STATEMENT
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"
Seek medical attention immediately at the first sign of any adverse drug reaction.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION
Store at temperatures not exceeding 30ºC.

KEEP OUT OF REACH OF CHILDREN.
SHAKE WELL BEFORE USE

AVAILABILITY
60 mL Amber Bottle (Box of 1's)

REGISTRATION NUMBER
DRP-10582

DATE OF FIRST AUTHORIZATION/RENEWAL
July 19,2012

DATE OF REVISION
December 2021

Manufactured by:
JM TOLMANN LABORATORIES, INC.
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