SALBUTAMOL

ACTIVENT TM

2 mg/5 mL Syrup

BRONCHODILATOR

FORMULATION:
Each 5 mL syrup contains:
Salbutamol (as sulfate), PP ..... 2 mg

PRODUCT DESCRIPTION:
Clear violet to pinkish-violet, grape-flavored syrup.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Salbutamol is used as bronchodilator in the management of reversible airway obstruction, as in asthma and in various forms of chronic obstructive pulmonary diseases.

Salbutamol is a direct-acting sympathomimetic amine with mainly beta-adrenergic activity. It acts selectively on beta-2 adrenergic receptors in the lungs to relax bronchial smooth muscle, thereby relieving bronchospasm and reducing airway resistance. It also relaxes the smooth muscle of the uterus and enhances vascular supply to the skeletal muscle. These are said to result from increased production of cyclic adenosine 3'5'-moophosphate (cyclic 3'5'-AMP) caused by activation of the enzyme adenyl cyclase.

Following oral administration, salbutamol is well absorbed from the gastrointestinal tract. It is metabolized in the liver and possibly in the gut wall. Estimated plasma half-life of salbutamol ranges from 4 to 6 hours.

Salbutamol is rapidly excreted mainly in the urine with 48-72 hours after oral administration, little portion is excreted via the feces.

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

DOSAGE AND ADMINISTRATION:
Adults (Syrup)
10 mL (2 teaspoonfuls) 3 - 4 times a day.
Or as prescribed by the physician.
Children (Syrup)
2 - 6 years: 2.5 mL - 5 mL (1/2 - 1 teaspoonful) 3 - 4 times a day.
7 - 12 years: 5 mL (1 teaspoonful) 3 - 4 times a day.
Over 12 years: 5 mL - 10 mL (1 - 2 teaspoonfuls) 3 - 4 times a day.

Or as prescribed by the physician.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:
Salbutamol (Activent) should not be used in patients with history of hypersensitivity to salbutamol.

Salbutamol should not be administered concomitantly with other sympathomimetic agent as it may cause adverse effects on the cardiovascular system.

Caution should be exercised in administering salbutamol to patients with thyroid disorders, myocardial insufficiency, arrhythmias, hypertension, susceptibility to QT-interval prolongation, and diabetes mellitus.

The bronchodilator effects of beta-agonist are opposed by non-cardioselective beta-blockers. Non-cardioselective beta blockers are contraindicated in asthmatic patients as they may cause serious bronchoconstriction. Normally, no adverse ineraction occurs between beta-agonist bronchodilators and cardioselective beta blocker; however, bronchospasm can occur in asthmatic patients particularly if high doses are used.

As the use of salbutamol with corticosteroids, diuretics or xanthenes increases the risk of hypokalemia, monitoring of potassium concentrations is recommended in severe asthma where such combination therapy is common.

DRUG INTERACTIONS:
Salbutamol should not be prescribed together with non-selective beta-adrenergic agents like propranolol.

The use of salbutamol with corticosteroids, diuretics and xanthenes may increase the risk of hypokalemia.

PREGNANCY AND LACTATION:
Most adverse effects of salbutamol in pregnancy relate to the cardiovascular and metabolic effects of the very high doses given by intravenous infusion to delay premature labor.

The use of salbutamol in lactating mothers is generally not recommended since It is not known whether salbutamol in breast milk has harmful effects on the neonate.

Pulmonary edema has been reported in pregnant women given with salbutamol for premature labor, although most cases are seen in patients given very high doses intravenously. Maternal effects include myocardial ischemia, unifocal ventricular ectopics associate with hypo-ischemic response to intravenous salbutamol and heart failure in hypersensitive women.

ADVERSE DRUG REACTIONS:
Salbutamol, like other beta-agonists, may cause fine tremors of the skeletal muscles specially the hands, nervous tension, hyperacidity, restlessness, headaches, increased heart rate, palpitations, tachycardia, hyperglycemia, peripheral vasodilation and rarely muscle cramps. The said effects which are common to all sympathomimetic drugs are dose-related.

Potentially serious hypokalemia and myocardial ischemia can occur in large doses. Hypersensitivity reactions including paradoxical bronchospasms, angioedema, urticaria, hypotension and collapse may also occur.

OVERDOSE AND TREATMENT:
Most common manifestations of overdose with salbutamol include nausea, vomiting, tachycardia, CNS stimulation, tremors, lactic acidosis, hypokalemia and hyperglycemia, Symptomatic management of these conditions has proved to be valuable.

In cases of oral overdose, activated charcoal may be considered, Appropriate medical management should be done or as recommended by the National Poison center.

AVAILABILITY:
60 mL Amber glass bottle

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

STORE AT TEMPERATURES NOT EXCEEDING 30oC.

PROTECT FROM LIGHT.

DR-XY16828

For suspected adverse drug reactions, report to the FDA: www.fda.gov.ph

SVMore

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Date of Renewal of Authorization: 10 September 2018
Date of Revision of Package insert: 9 July 2018