Primera

SALBUTAMOL

PRIMESAL

2 mg / 5 mL SYRUP

BRONCHODILATOR

℞

FORMULATION:
Each 5 mL (1teaspoonful) contains:
Salbutamol (as sulfate)……2 mg

PRODUCT DESCRIPTION:
Salbutamol 2 mg / 5 mL (Primesal) Syrup used to treat breathing problems in people with asthma and similar conditions. Salbutamol (Primesal) Syrup is a cherry red colored syrup with strawberry flavor.

PHARMACODYNAMICS:
Salbutamol (Primesal) is a sympathomimetic agent with a relatively selective action on beta 2 adrenoceptor agonist. The action of salbutamol is to stimulate adenylyl cyclase which catalyzes the formation of cAMP. The cAMP formed and mediates smooth muscle relaxation and bronchodilation.

PHARMACOKINETICS:
Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. After multiple oral doses of salbutamol 4 mg four times a day, steady-state plasma concentrations are obtained after 3 days. About half is excreted in the urine as an inactive sulfate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%.

INDICATIONS:
For chronic management or prophylactic therapy of bronchial asthma.

DOSAGE AND ADMINISTRATION:
Adult:
10 mL (2 teaspoonfuls) taken 3 to 4 times daily.
Children:
2 to 6 yrs. old
2.5 – 5 mL (1/2 - 1 teaspoonful) taken 3 to 4 times daily.
6 to 12 yrs. old
5 mL (1 teaspoonful) taken 3 to 4 times daily.
Over 12 years of age
5-10 mL (1-2 teaspoonfuls) taken 3 to 4 times daily or as prescribed by the physician.

CONTRAINDICATIONS:
Patients with marked liver parenchymal damage also in patients with severe renal insufficiency when repeated determinations of the plasma concentrations cannot be made.

PRECAUTIONS:
Salbutamol should be used with caution in patients who may be particularly susceptible to their effects, particularly those with hyperthyroidism. Also in patients with cardiovascular disease, arrhythmia, tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension or aneurysms. Angina pains may be precipitated in patients with angina pectoris. Care is required when salbutamol is given to patients with diabetes mellitus or closed angle glaucoma.

PREGNANCY AND LACTATION:
Pregnancy:
They have rare various cases of report of congenital anomalies such as cleft palate and limb defects in the offspring of patients treated with salbutamol. Drug administration of salbutamol during pregnancy should only be considered if the expected benefit to the mother is beyond than any possible risk to the fetus.
Lactation:
Salbutamol may be secreted in breast milk, do not administer to breastfeeding women, unless it is prescribed by the physician. The expected benefit to the drug is beyond than any potential risk to the baby.

DRUG INTERACTIONS:
Patients who are under medication of non-Selective Beta blockers such as propranolol should not be prescribed together with salbutamol. Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants since the action of salbutamol on the cardiovascular system may be potentiated.

ADVERSE DRUG REACTION:
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common(≥1/100 to ≤1/10), uncommon (≥1/1000 to ≤1/100), rare (≥1/10,000 to ≤1/1,000) and very rare (≤1/10,000) including isolated reports. Very common and common reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data.

Immune system disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.
Metabolism and nutrition disorders
Rare: Hypokalemia
Potentially serious hypokalemia may result from beta2 agonist therapy.
Nervous system disorders
Very common: Tremor
Common: Headache
Very rare: Hyperactivity
Cardiac disorders
Common: Tachycardia, palpitations.
Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.
Vascular disorders
Rare: Peripheral vasodilation
Musculoskeletal and connective tissue disorders
Common: Muscle cramps
Very rare: Feeling of muscle tension

OVERDOSAGE AND TREATMENT:
Overdosage may cause peripheral vasodilation and increased irritability of skeletal muscle, hypokalemia, tachycardia, arrhythmia, and hypertension and in severe cases may result to sudden death. Serum potassium levels should be monitored. Nausea, vomiting and hyperglycemia have been reported, predominantly in children and when salbutamol overdose has been taken by oral administration. Treatment consideration should be given to discontinuation of treatment and appropriate symptomatic therapy. In case of overdosage, gastric lavage should be performed. In order to antagonize the effect of salbutamol, the use of a beta-adrenergic blocking agent preferably one of the relatively cardioselective ones such as metoprolol and atenolol may be considered, bearing in mind the danger of inducing an asthmatic attack.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Protect from light.

AVAILABILITY:
Salbutamol 2 mg/5 mL (Primesal) Syrup - 60 mL Amber Bottle

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

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.

REGISTRATION NUMBER:
Salbutamol 2 mg/5 mL (Primesal) Syrup: DR-XY20830-B

DATE OF FIRST AUTHORIZATION:
Salbutamol 2 mg/5 mL (Primesal) Syrup – January 16, 1996

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