Salbutamol

Asmalin®

2 mg / 5 mL SYRUP

Anti-asthma

FORMULATION

Each 5 mL (1 teaspoonful) contains:

Salbutamol (as sulfate) ..... 2 mg

PRODUCT DESCRIPTION

Salbutamol (Asmalin®) 2 mg/5 mL Syrup is a red-colored, clear syrup with fruity strawberry odor and sweet strawberry taste using the TasteRite™ Technology. TasteRite™ technology is a unique tastemasking system developed specifically for liquid dosage forms to improve the taste of the medicine.

PHARMACODYNAMICS

Salbutamol is a selective short-acting β_2-adrenergic agonist with preferential effect on β_2-adrenergic receptors found in the respiratory tract. It stimulates adenyl cyclase, the enzyme which catalyzes the conversion of adenosine triphosphate (ATP) to cyclic-3',5'-adenosine monophosphate (cAMP). cAMP mediates cellular responses such as bronchial smooth muscle relaxation resulting in bronchodilation.

PHARMACOKINETICS

Salbutamol is readily absorbed from the gastrointestinal tract. Bronchodilation begins within 30 minutes after oral administration, with peak effect in 2 to 3 hours, and may persist up to 4 to 6 hours. It is extensively metabolized in the liver, being converted to salbutamol 4'*O*-sulfate. Salbutamol and its metabolites are rapidly excreted in urine and feces. Following oral administration of salbutamol to healthy individuals, about 76% of a single dose is excreted in urine within 72 hours, mainly as the major metabolite; about 4% of the dose is excreted in feces.

INDICATION

For the relief of bronchospasm associated with reversible obstructive airway diseases such as bronchial asthma and chronic obstructive pulmonary disease.

DOSAGE AND ADMINISTRATION

Orally, every 6 to 8 hours, or, as prescribed by a physician.
Children
Under 2 years ..... as prescribed by a physician
2 to 6 years ..... 2.5 to 5 mL (1/2 to 1 teaspoonful)
7 to 12 years ..... 5 mL (1 teaspoonful)
Adults and children over 12 years ..... 5 to 10 mL (1 to 2 teaspoonsful)

CONTRAINDICATION

- Hypersensitivity to salbutamol or to any ingredient of the product
- Certain maternal or fetal conditions may contraindicate tocolytic therapy (e.g., eclampsia or severe preeclampsia, intrauterine infection, intrauterine fetal death, antepartum hemorrhage, placenta praevia, cord compression, or toxemia of pregnancy); salbutamol should not be used for threatened abortion

WARNING AND PRECAUTIONS

Paradoxical Bronchospasm
Paradoxical bronchospasm, a potentially life-threatening event, has been observed with salbutamol. If it occurs, discontinue use of the product immediately.

Deterioration of Asthma
Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. Increased use of β_2-agonists, especially daily use, is a sign of deterioration of asthma control and indicates the need to reassess treatment. Possible need for anti-inflammatory treatment (e.g., corticosteroids) should be considered.

Hypokalemia
Therapy with salbutamol and other β_2-agonists may produce decrease in plasma potassium concentration possibly through intracellular shunting resulting in cardiovascular undesirable effects.

Use with caution in acute severe asthma where concomitant therapy with steroid, xanthine derivatives, or diuretics, and by hypoxia may result in hypokalemia; potassium concentrations should be monitored in severe asthma.

Coexisting Conditions
Use with caution in patients with the following conditions:
- Cardiovascular disorders including coronary insufficiency, cardiac arrhythmias, or hypertension: Salbutamol, like all other β_2-agonists, can produce clinically significant cardiovascular effects such as changes in pulse rate or blood pressure.
- Convulsive disorders
- Hyperthyroidism
- Diabetes mellitus
- In patients who are unusually responsive to sympathomimetic amines

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INTERACTIONS WITH OTHER MEDICATIONS

Sympathomimetic agents: Salbutamol should not be administered concomitantly with other short-acting sympathomimetic aerosol bronchodilators or epinephrine. If additional sympathomimetic agents are to be administered by any route, these agents should be used with caution to avoid deleterious cardiovascular effects.

Beta-adrenergic blocking agents: Beta-adrenergic blocking agents may inhibit the effect of ß-agonists such as salbutamol. It may also produce severe bronchospasm. These drugs should be administered with caution.

Diuretics: Administration of nonpotassium-sparing diuretics (e.g., loop or thiazide diuretics) may result in ECG changes/and or hypokalemia and can be acutely worsened by administration of ß-agonists such as salbutamol, especially when the recommended dose of the ß-agonist is exceeded.

Digoxin: Following administration of single-dose intravenous or oral salbutamol to healthy individuals who had received digoxin for 10 days, a 16% to 22% decrease in serum digoxin concentration was observed. Although the clinical importance of these findings for patients who are receiving inhaled salbutamol and digoxin on a chronic basis is unclear, patients receiving such concomitant therapy should have their serum digoxin concentration carefully evaluated.

Monoamine oxidase inhibitors (MAOIs) or Tricyclic antidepressants (TCAs): Salbutamol should be used with caution in patients receiving MAOIs or TCAs, or within 2 weeks of discontinuation of such agents, because the effect of salbutamol on the vascular system may be potentiated. Alternative therapy should be considered in patients taking MAOIs or TCAs.

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy: **Pregnancy Category C.** There have been reports of congenital anomalies (e.g., cleft palate and limb defects) in children of patients treated with salbutamol. Some of the mothers, however, were receiving various medications in the course of their pregnancies. Since there is no consistent pattern of congenital abnormality development, a relationship between the use of salbutamol and the development of congenital anomalies cannot be established. Therefore, salbutamol should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: Since β_2-agonists may interfere with uterine contraction, the product should be used in labor only if the potential benefit justifies the potential risk.

Lactation: Salbutamol may be secreted in breast milk. Therefore, do not administer to breastfeeding women unless, in the opinion of a physician, the potential benefit of the drug justifies the potential risk.

UNDESIRABLE EFFECTS

Local, Sensitivity and Dermatologic: Hypersensitivity reactions (urticaria, angioedema, rash, bronchospasm, anaphylaxis, oropharyngeal edema, hypotension, collapse), increased sweating, erythema multiforme including Stevens-Johnson syndrome

Endocrine and metabolic disorders: Hypokalemia

Nervous system: Tremors, headache, hyperactivity, nervousness, dizziness, vertigo, central nervous stimulation

Cardiovascular: Tachycardia, palpitations, hypertension, hypotension, cardiac arrythmias (including atrial fibrillation, supraventricular tachycardia, and extrasystoles), myocardial ischemia, peripheral vasodilation, angina

Respiratory/Nasopharyngeal: Paradoxical bronchospasm, cough

Gastrointestinal: Nausea and/or vomiting, increased appetite, epigastric pain, stomachache

Musculoskeletal: Muscle cramps

Ocular: Conjunctivitis

OVERDOSE AND TREATMENT

Symptoms of salbutamol overdose include extensions of the common undesirable effects (e.g., seizures, hypertension or hypotension, arrhythmias, palpitation, nervousness, dizziness, fatigue, malaise, insomnia/sleeplessness, headache, tremor, dry mouth, and nausea). Angina and tachycardia have also occurred following overdosage. Hypokalemia has also been reported; thus, plasma-potassium concentrations should be monitored.

Discontinue salbutamol and institute appropriate symptomatic therapy in cases of salbutamol overdosage. Administration of a beta-adrenergic blocking agent may be appropriate, but use with caution if the patient is asthmatic.

STORAGE CONDITIONS

Always keep the container tightly closed.

Keep the product out of reach and sight of children.

Store at temperatures not exceeding 25°C.

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

AVAILABILITY
In 60 mL bottles.

DATE AND REVISION OF PACKAGING INSERT: March 2016

Manufactured by AMHERST LABORATORIES, INC.
Unilab Pharma Campus, Barangay Mamplasan
Binan, Laguna, Philippines
for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Trusted Quality Healthcare

TOGETHER WE CAN BEAT CHILDHOOD ASTHMA
Child Asthma Network