# SALBUTAMOL sulfate

# ASMACAIRE

1 mg / mL Solution for Inhalation

**BRONCHODILATOR**

**FORMULATION:**
Each mL contains:
Salbutamol (as sulfate), BP ..... 1mg
"STERILE"

**DESCRIPTION:**
A solution is clear, colourless and free from extraneous particles. Salbutamol is a direct-acting sympathomimetic with predominantly beta-adrenergic activity and a selective action on beta receptors. This results in its bronchodilating action being more prominent that its effect on heart.

**PHARMACOLOGICAL PROPERTIES**
**Pharmacodynamic properties:**
Pharmacotherapeutic group: Andrenergics, inhalants. Selective beta-2-andrenoreceptor agonists.

Salbutamol is a selective β2-agonist providing short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction. At therapeutic doses it acts on the β2-adrenoceptors of bronchial muscle. With its fast onset of action, it is particularly suitable for the management and prevention of attack in asthma.

**Pharmacokinetic properties**
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally, and partly by metabolism to the inactive 4'-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine. The feaces are a minor route of excretion. Most of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

After administration by the inhaled route between 10 and 20% of the dose reaches the lower airways. The oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation, but is not metabolised by the lung. On reaching the systemic circulation it becomes accessible to hepatic meatabolism and is excreted, primarily in the urine, as unchange drug and as the phenolic sulfate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Both unchanged drug and conjugate are excreted primarily in the urine.

**INDICATIONS:**
Salbutamol sulfate is indicated in the treatment of acute severe asthma and routine management of chronic bronchospasm unresponsive to conventional therapy. Its main clinical use is in asthma. It may be used for the symptomatic relief of an acute attack, as a part of the emergency treatment of acute severe asthma, and as a part of the long-term chronic therapy.

**DOSAGE AND ADMINISTRATION:**
**Adults and Children:**
A suitable starting dose of Salbutamol by wet aerosol is 2.5 mg (one nebule) but this maybe increased to 5 mg. Treatment may be repeated up to four times daily by means of a nebulized. Delivery of the aerosol maybe by face mask of "T" piece. Salbutamol sulfate 2.5 mg are intended to be used undiluted. However of prolonged delivery time is desirable (more than 10 times) dilution with sterile distilled water or normal saline for injection may be required.
Or as prescribed by the physician.

**DIRECTION FOR USE:**
The product should be used with a respirator or nebulizer only, under the direction of a physician. It is not to be injected or administered orally.
To open the nebules, twist off the cap.
Squeeze the content into the reservoir of the nebulizing chamber
Discard the nebules after use.

**CONTRAINDICATION:**
Salbutamol sulfate is contraindicated in patients with a history of hypertensitivity or to any of its component.

**PRECAUTIONS:**
Sympathomimetic agents should be used with caution in patients who may be particularly susceptible to their effects, particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension, or aneurysms. Anginal pain may be precipitated in patients with angina pectoris. Excessive administration of sympathomimetic agents to the nasal mucosa may produce rebound congestion and rhinorrhea. Care is also required when sympathomimetic agents are given to patients with diabetes mellitus or closed-angle glaucoma. Sympathomimetic agents should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation. An increased risk of arhythmias may also occur if sympathomimetic agents are given to patients receiving cardiac glycosides, quinine, or tricyclic antidepressants. Salbutamol nebules 2.5 mg should be used with care in patients known to have received large doses of other sympathomimetic drugs. They should be administered cautiously to patients from thyrotoxicosis.

**WARNINGS**:
Salbutamol sulfate 2.5 mg is to used with a nebulizer, or under the direction of a physician. The solution should not be injected or administered orally. Patients receiving treatment at home with Salbutamol sulfate 2.5 mg must be warned that if either the usual relief is diminished or the usual duration of action was reduced, they should not increase the dose or its frequency of administration, but should seek medical advices.Unnecessary administration of drugs during the first trimester of pregnancy is undesirable.

**SIDE EFFECTS:**
**Undesirable effects**
Adverse events 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<1/1000) and very rare (<1/10,000). Very common and common events were generally determined from clinical trial data. Rare, very rare and unknown events 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: Hypokalaemia.
Potentially serious hypokalaemia may result from beta2 agonist therapy.
Unknown: Lactic acidosis

**Nervous system disorders**
Common: Tremor, headache.
Very rare: Hyperactivity.

**Cardiac disorders**
Common: Tachycardia.
Uncommon: Palpitations
Very rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasytoles
Unknown: Myocardial ischaemia*

**Vascular disorders**
Rare: Peripheral vasodilation.
Respiratory, thoracic and mediastinal disorders
Very rare: Paradoxical bronchospasm.

**Gastrointestinal disorders**
Uncommon: Mouth and throat irritation.

**Musculoskeletal and connective tissue disorders**
Uncommon: Muscle cramps.
* reported spontaneously in post-marketing data therefore frequency regarded as unknown.

**DRUG INTERACTIONS:**
Other short-acting sympathomimetic aerosol bronchodilators or epinephrine should not be used concomitantly with Salbutamol sulfate. If additional adrenergic drugs are to be administered by any route, they shoul be used with caution to avoid deleterious cardiovascular effects.

**OVERDOSAGE:**
The preferred antidote to overdosage with Salbutamol sulfate is cardioselective beta-blocking agent, but beta blocking drugs should be used with caution in patients with a history of bronchospasm.

**FERTILITY, PREGNANCY AND LACTATION:**
Pregnancy
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. As with the majority of drugs, there is little published evidence of the Salbutamol in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the fetus at very high dose levels.

Lactation
As salbutamol is probably secreted in breast milk, its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, and so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

Fertility
There is no information on the effects of Salbutamol on human fertility.
There were no adverse effects on fertility in animals.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:**
None reported.

**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 Acts prohibits dispensing without prescription.

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

**AVAILABILITY**
Clear Plastic Nebule x 2.5 mL (Box of 35's)

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