Salbutamol
Asmalin®

1 mg / mL
SOLUTION FOR NEBULIZATION
Anti-Asthma

Formulation:
Each 2.5 mL of the solution contains:
Salbutamol (as sulfate) ..... 2.5 mg

Description:
Salbutamol (as sulfate) 1 mg/mL Solution for Nebulization (Asmalin®) is a sterile, isotonic solution of Salbutamol Sulfate in Water for Injection. It contains no preservative. Its chemical formula is $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$. It is also known as Albuterol Sulfate (USAN). Salbutamol Sulfate 1.2 mg is approximately equivalent to 1 mg of salbutamol base.

Pharmacology:
Salbutamol is a selective Beta $_2$ adrenergic agonist which, in therapeutic doses, acts selectively on receptors in the bronchial muscles with little or no effect on the cardiac receptors. Its behavior following inhalation depends on the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. Its plasma half-life is from 2 to 7 hours, with the longer value following aerosol inhalation.

Indications:
Salbutamol is used as a bronchodilator for the symptomatic relief of bronchospasm in obstructive airway diseases like bronchial asthma, emphysema, and chronic bronchitis. In moderate to severe or unresponsive asthma, salbutamol is given via a nebulizer.

Dosage:
Salbutamol (as sulfate) 1 mg/mL Solution for Nebulization (Asmalin®) is given at a dose of 2.5 to 5 mg via a nebulizer, to be repeated up to 4 times daily or as prescribed by the physician. For faster delivery time, this may be used undiluted. If prolonged delivery time is desired, dilution with an equal amount of 0.9% Sodium Chloride solution may be done. E.g. **Salbutamol (as sulfate) 1 mg/mL Solution for Nebulization (Asmalin®)** 2.5 mL diluted in 2.5 mL of 0.9% Sodium Chloride Solution. Discard any solution left in the nebulizer after each treatment.

Precautions:
1. Administer with caution to patients with cardiovascular diseases like ischemic heart disease, arrhythmia or tachycardia, hypertension, occlusive vascular disorders including arteriosclerosis, and aneurysms.
2. Administer with caution in patients with convulsive disorders, hyperthyroidism or diabetes mellitus.
3. Anginal pain may be precipitated in patients with angina pectoris.
4. Administer with caution to patients taking other sympathomimetic drugs.
5. Instruct patients receiving treatment at home to seek medical advice if usual relief is not obtained after the usual dose, or if the usual duration of effectiveness is reduced. THE DOSE SHOULD NOT BE INCREASED.
6. Adjustment of dose and frequency of administration should only be by medical advice.
7. Salbutamol should be used by lactating mothers only if the overall benefits outweigh any potential risk.
8. Salbutamol is not indicated for the prevention of premature labor associated with toxemia of pregnancy or antepartum hemorrhage.
9. Give cautiously to patients with hypokalemia, as this may result in increased susceptibility to digitalis-induced cardiac arrhythmias.

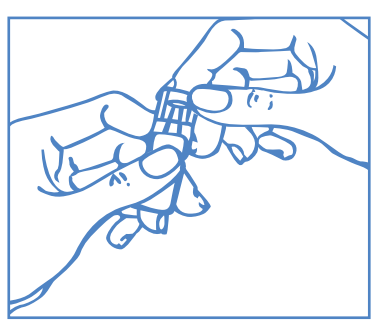
Contraindications:
1. Hypersensitivity to the drug or any of its components
2. Thyrotoxicosis
3. Threatened abortion during the first and second trimesters of pregnancy. There is no definite proof as to the safety of the drug to the fetus in the early stages of pregnancy.

Drug Interactions:
1. Effect of high doses of salbutamol may be exacerbated by concomitant administration of high doses of corticosteroids.
2. Salbutamol effects are antagonized by propranolol or other beta-receptor blocking agents.
3. Concomitant aminophylline or xanthine administration may enhance the salbutamol effects.
4. Hypokalemia associated with high doses of salbutamol may increase the susceptibility to digitalis-induced cardiac arrhythmias.

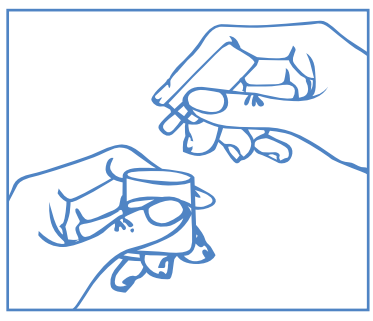
Adverse Effects:
1. Tachycardia, palpitations, flushing
2. Fine tremors of skeletal muscles, particularly of the hands
3. Feeling of nervousness and tension, headaches, muscle cramps

Toxicity:
Overdosage is manifested by severe muscle tremors and significant tachycardia. The antidote is any cardioselective beta-blocking agent given intravenously.

Instructions For Use:
1. Twist off head to open the ampoule.



2. Place prescribed amount into the nebulizer bowl.



Storage Instructions:
1. Store at temperature not exceeding 30 °C.
2. Protect from light. Place inside the aluminum pouch after each use.
3. Discard unused portion of the ampoule three months after opening the aluminum pouch.

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

Availability:
Salbutamol (as sulfate) 1 mg/mL Solution for Nebulization (Asmalin®)
is available in 2.5 mL ampoules of low-density polyethylene.

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Manufactured by:
EURO-MED® LABORATORIES PHIL., INC.
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