Salbutamol

Salbo®

℞

100mcg

Pressurized Metered Dose Inhaler
Selective Beta-2-Adrenoreceptor Agonist

PRODUCT DESCRIPTION
Salbutamol (Salbo) 100mcg is a pressurized metered dose inhaler consisting of an aluminum canister with metering valve containing pressurized liquid, fitted over a bluish green color actuator along with a dark bluish green color cap. Upon spraying on black sheet white smear will appear. Each canister contains at least 200 actuations.

FORMULATION
Salbutamol (Salbo) inhaler is available for administration as:

Salbo inhaler 100mcg
Each actuation delivers
Salbutamol (as sulfate), BP ... 100mcg

CLINICAL PHARMACOLOGY
PHARMACODYNAMICS
Salbutamol is a selective $ß_2$-adrenoceptor agonist. At therapeutic doses it acts on the $ß_2$-adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

PHARMACOKINETICS
Absorption and Distribution
After administration by the inhaled route between 10% and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation, but is not metabolized by the lung.
Salbutamol is bound to plasma proteins to the extent of 10%.

Metabolism and Excretion
The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. The portion deposited in the lung is not metabolized by the lung. On reaching the systemic circulation it becomes accessible to hepatic metabolism and is excreted primarily in the urine as unchanged drug and as the phenolic sulfate.
Most of the dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours.

THERAPEUTIC INDICATIONS
Salbutamol (Salbo) inhaler is indicated in adults, adolescents and children aged 4 to 11 years.
Salbutamol (Salbo) inhaler provides short-acting (4-6 hours) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction.
It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur and to prevent them in those circumstances recognized by the patient to precipitate an asthma attack (e.g., before exercise or unavoidable allergen exposure).
Salbutamol (Salbo) inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

DOSAGE AND ADMINISTRATION
Salbutamol (Salbo) inhaler 100mcg is for oral inhalation use only.
The dose is expressed in terms of inhalations, each inhalation delivers 100mcg of salbutamol.

Condition	Adult Dose	Children ≥ 12 Years Dose	Children < 12 Years Dose
Acute asthma symptoms including bronchospasm	1 inhalation as a single minimum starting dose. This may be increased to 2 inhalations if necessary	1 inhalation as a single minimum starting dose. This may be increased to 2 inhalations if necessary	1 inhalation. The dose may be increased to 2 inhalations if required
Chronic therapy	2 inhalations up to 4 times a day	Up to 2 inhalations 4 times a day	Up to 2 inhalations 4 times a day
Prevention of allergen or exercise-induced symptoms	2 inhalations 10-15 minutes before challenge	2 inhalations 10-15 minutes before challenge	1 inhalation before challenge or exertion. The dose may be increased to 2 inhalations if required.
Total daily dose should not exceed 8 inhalations in any 24 hours.			

Instructions for Use
Patients should be instructed in the proper use of their inhaler. During inhalation, the patient should preferably sit or stand.

Testing the inhaler:
Before using for the first time or if your inhaler has not been used for a week or more remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release one puff into the air to make sure that it works.

Cleaning:
Your inhaler should be cleaned at least once a week.
- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover.

Do not put the metal canister in water.

ADVERSE EFFECTS
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
Common: Tremor, headache
Very rare: Hyperactivity

Cardiac disorders
Common: Tachycardia
Uncommon: Palpitations
Very rare: cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles)
Unknown: Myocardial ischemia

Vascular disorders:
Rare: Peripheral vasodilatation

Respiratory, thoracic and mediastinal disorders
Very rare: Paradoxical bronchospasm

Gastrointestinal disorders
Uncommon: Mouth and throat irritation

Musculoskeletal and connective tissue disorders
Uncommon: Muscle cramps

215mm

150mm

215mm

CONTRAINDICATIONS
- Salbutamol is contraindicated in patients with hypersensitivity to any component of this product.
- Salbutamol must not be used to arrest uncomplicated premature labor or threatened abortion.

PRECAUTIONS
- Patient's inhaler technique should be checked to make sure that inhaler actuation is synchronized with inspiration of breath for optimum delivery of drug to the lungs.
- In the event of a previously effective dose of inhaled salbutamol failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken.
- Salbutamol should be administered cautiously to patients with hyperthyroidism, convulsive disorders, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension and diabetes mellitus.
- Potentially serious hypokalemia may result from $ß_2$ agonist therapy mainly from parenteral and nebulized administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.
- Patients requiring long-term management with bronchodilators should be kept under regular surveillance.
- Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. Patients with underlying severe heart disease (e.g., ischemic heart disease, arrhythmia or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnea and chest pain as they may be of either respiratory or cardiac origin.
- Increasing use of short-acting inhaled $ß_2$-agonists to control symptoms indicates deterioration of asthma control. Consideration should be given to starting or increasing corticosteroid therapy.
- Inhaled salbutamol can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs, salbutamol should be discontinued immediately and alternative therapy instituted.
- If immediate hypersensitivity reactions occur, discontinue salbutamol.
- Salbutamol should be administered cautiously to patients with thyrotoxicosis.

Pregnancy
The use of salbutamol during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.

Nursing Mothers
Salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk.

Drug Interaction
- Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants or within 2 weeks of discontinuation of such agents, because the action of salbutamol on the cardiovascular system may be potentiated.
- ß-adrenergic-receptor blocking agents not only block the pulmonary effect of $ß_2$-agonists, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with ß-blockers.
- Use of salbutamol and other $ß_2$-agonists with corticosteroids, diuretics or xanthines increases the risk of hypokalemia and monitoring of potassium concentrations is recommended in severe asthma where such combination therapy is common.

OVERDOSAGE AND TREATMENT
The most common signs and symptoms of overdose with salbutamol are transient $ß_2$-agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalemia. Serum potassium levels should be monitored.
Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy such as cardio-selective ß-blocking agents in patients presenting with cardiac symptoms (e.g., tachycardia, palpitations).
ß-blocking drugs should be used with caution in patients with a history of bronchospasm.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.
Protect from heat, frost and direct sunlight.

Pressurized can. Do not puncture, break or burn even when apparently empty.
As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold.
The expiration date refers to the product correctly stored at the required conditions.

Keep all medicines out of reach of children.

AVAILABILITY
Salbutamol (Salbo) 100mcg pressurized metered dose inhaler is available as aluminum canister x 200 actuations (box of 1's)

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

For suspected adverse drug reaction, report to FDA: www.fda.gov.ph
The patient is advised to seek immediate medical attention at the first sign of adverse drug reaction.

REGISTRATION NUMBER: DR-XY47359

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Please read the contents carefully before use.
This package insert is continually updated from time to time.

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150mm