SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG PRODUCT

Salboget Pressurized Inhalation 100mcg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains:
Salbutamol…100mcg
(as Salbutamol Sulfate Ph. Eur.)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pressurized inhaler.

Aluminum canister with metering valve containing pressurised 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.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Salboget (Salbutamol) Pressurised Inhalation 100mcg is indicated in adults, adolescents and children aged 4 to 11 years.
Salboget (Salbutamol) Pressurised Inhalation 100mcg 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).
Salboget (Salbutamol) Pressurised Inhalation 100mcg 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.

4.2 Posology and Method of Administration

Salboget (Salbutamol) Pressurised Inhalation 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 two 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.

4.3 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.

4.4 Special warnings and special precautions for use

- 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 diabetic mellitus.
- Potentially serious hypokalemia may result from ß2 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 ß2-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.

4.5 Interaction with other medicinal products and other forms of Interactions

- 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 ß2-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 ß2-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.

4.6 Pregnancy and Lactation

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.

4.7 Effects on ability to drive and use machines

Salbutamol may cause dizziness. If you are affected do not drive or operate machinery.

4.8 Undesirable effects

Adverse reactions are presented below by System Organ Class (SOC) and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), and very rare (<1/10,000), including isolated reports. Very common and common adverse reactions were generally derived from clinical trial data, whereas rare, very rare and adverse reactions of unknown frequency were generally identified from spontaneous post-marketing reports.

System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Very rare	Hypersensitivity reactions, including angioedema, urticaria, bronchospasm, hypotension and collapse
Metabolism and nutrition disorders	Rare	Hypokalaemia
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 ischaemia
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

Additional information:
Hypokalaemia may occur as a result of beta-2 agonist therapy and may be potentially serious.

* Myocardial ischaemia was reported spontaneously in post-marketing data; therefore, its frequency is considered unknown.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdosage

The most common signs and symptoms of overdose with salbutamol are transient ß2-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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Selective beta-2-andrenoreceptor agonists
ATC Code: R03AC02
Salbutamol is a selective ß2-adrenoceptor agonist. At therapeutic doses it acts on the ß2-adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

In common with other potent selective β2-agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of fetuses were found to have cleft palate at 2.5mg/kg dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant fetal abnormalities.
The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. Reproductive studies in the rabbit at doses of 50mg/kg/day orally (i.e. much higher than the normal human dose) have shown fetuses with treatment related changes; these included open eyelids (ablepharia), secondary palate clefts (palatoschisis), changes in ossification of the frontal bones of the cranium (cranioschisis) and limb flexure. Reformulation of the Salbutamol Evohaler has not altered the known toxicological profile of salbutamol.

In an oral fertility and general reproductive performance study in rats at doses of 2 and 50 mg/kg/day, with the exception of a reduction in number of weanlings surviving to day 21 postpartum at 50 mg/kg/day, there were no adverse effects on fertility, embryofetal development, litter size, birth weight or growth rate.

The non-CFC propellant, HFA 134a, has been shown to have no toxic effect at very high vapour concentrations, far in excess of those likely to be experienced by patients, in a wide range of animal species exposed daily for periods of two years.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Oleic acid
- Ethanol Absolute
- Propellant HFA 134a

6.2 Incompatibilities

None

6.3 Shelf-life

2 Years
The expiration date refers to the product correctly stored in the required conditions.

6.4 Special precautions for storage

- Do not store above 30°C.
- Protect from direct sunlight, heat and frost.
- Shake well before use.

6.5 Nature and contents of container

Salboget (Salbutamol) Pressurised Inhalation 100mcg is available in a pack of 1's in a unit carton along with the package insert. Each canister provides 200 metered doses.

6.6 Special precautions for disposal

No special requirements.

6.7 Instructions for use/handling

- Keep out of reach of children.

- To be sold on prescription of a registered medical practitioner only.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

H2024/CTD7666/14848

9. DATE OF PRODUCT REGISTRATION ISSUED

July 31, 2024

10. DATE OF REVISION OF THE TEXT

24/08/2026