Características Técnicas

IBERGRAF OFFSET GRAFIQUES ANDREU COLL S.L.

Cliente: LAB. ALDO-UNION, S.L. **H.P.:** 14317

Producto: HEALOL SALBUTAMOL INHALER (HEALOL-MALASIA)

Código: 510460/C-19 **Anula a:** AL MISMO

Papel: OFFSET **Gramaje:** 60g **C. Barras:** 633

Medidas: 185 x 270 mm **Medidas Plegado:** SIN PLEGAR

Tipografía: TRAZADA

Colores: 1+1 NEGRO **C.I.:** 91815

Fecha: 16 / 09 / 2024	**A corregir** **Aprobado**	**Fecha y Firma**

Package Insert

For the use of Registered Medical Practitioner or Hospital or a Laboratory only.

Name of Product
Healol Salbutamol Inhaler (Salbutamol 100 mcg/dose).

Name and Strength of Active Ingredient
Each actuation delivers
Salbutamol ……..100 mcg
Suspended in Propellant 134a…….q.s

Dosage form
Pressurized Inhalation.

Product Description
Healol Salbutamol Inhaler is a white homogenous suspension aerosol for inhalation, in propellant HFA – 134a, supplied in a pressurized container.
Nature and content: Aluminium container with 200 actuations, each containing 100 micrograms of salbutamol, fitted with a metered-dose valve, activator-oral adapter, and cap.

Pharmacodynamics/Pharmacokinetics
Pharmacodynamics
Salbutamol is a selective β2 adrenoceptor agonist. At therapeutic doses it acts on the β2 adrenoceptors of bronchial muscle, with little or no action on the β1 adrenoceptors of cardiac muscle. It is suitable for the management and prevention of attack in asthma.

Pharmacokinetics
Salbutamol MDI provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airway obstruction.
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'-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority 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 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 metabolised 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 sulphate. The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine.

Indication
Indicated 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). Indicated 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
Adults and children over four years of age
For the relief of acute episodes of bronchospasm or prevention of asthma symptoms: One or two Inhalations four times daily. If control of mild asthma deteriorates and results in regular use of a short acting β2 -agonist more than 4 times daily, patients should be instructed to contact a clinician for revaluation and possible Institution of maintainence therapy.
To prevent exercise-induced bronchospasm: Two inhalations 15 minutes prior to exercise.

Children below. 4 years of age: Safety and effectiveness of Inhaled salbutamol have not been established.

Mode of administration
Oral Inhalation.

Contraindication
Hypersensitivity to salbutamol or any of the components of the formulation.

Warning and Precautions
The management of asthma should normally follow a stepwise program, and patient response should be monitored clinically and by lung function tests.
Increasing use of short-acting inhaled β2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.
In the event of a previously effective dose of inhaled Salbutamol MDI 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.
The patient's inhaler technique should be checked to make sure that aerosol actuation is synchronized with inspiration of breath for optimum delivery of the drug to the lungs.
Salbutamol should be administered cautiously to patients with thyrotoxicosis.
Potentially serious hypokalaemia may result from β2 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.
Effect on ability to drive and use machines – none known.

Pregnancy and Lactation
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 salbutamol is probably secreted in breast milk its use in nursing mothers, is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

Side Effects
Salbutamol MDI may cause a fine tremor of skeletal muscle, usually the hands are obviously affected. This effect is common to all beta-adrenergic stimulants.
Occasionally headaches have been reported.
Peripheral vasodilatation and a compensatory small increase in heart rate may occur in some patients.
Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse have been reported very rarely.
There have been very rare reports of muscle cramps.
As the other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. Salbutamol Respirator Solution and Salbutamol Solution for Inhalation should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted.
Potentially serious hypokalaemia may result from β2 agonists therapy.
As with other β2 agonists hyperactivity has been reported rarely in children. Mouth and throat irritation may occur with inhaled salbutamol.
Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) may occur in some patients.
Tachycardia may occur in some patients.

Symptoms and Treatment of Overdose
Overdose should receive symptomatic treatment.
The preferred antidote in the case of salbutamol overdose is a cardioselective beta-blocker. However, beta-blockers must be used with caution in patients with a history of bronchospasm. Hypokalaemia may occur as a result of salbutamol overdose. The serum potassium levels must be monitored, with potassium replacement via the oral route, except in patients with severe hypokalaemia, where the intravenous route may prove necessary.
Overdose symptoms are those of excessive β-stimulation, e.g. seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue and insomnia.

Interactions with Other Medication
Salbutamol should not be administered together with other inhaled sympathomimetic bronchodilators. If additional adrenergic drugs must be administered by any route, they should be used with caution in order to avoid harmful cardiovascular effects. Salbutamol must be administered with caution in patients treated with monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants, since they can increase the action of salbutamol on the vascular system.
Salbutamol and non-selective beta-blockers such as propranolol should not usually be administered together. Likewise, caution is recommended in patients receiving cardiac glycoside treatment. Potentially serious hypokalaemia has occurred as a consequence of systemic treatment with beta-2-agonists. Particular caution is advised in the case of severe acute asthma, since this effect can be potentiated by concomitant treatments with xanthine derivatives, corticosteroids and diuretics, and by hypoxia.
Since salbutamol can decrease serum potassium levels, caution is required in patients who are receiving serum potassium-lowering drugs, since the effects may prove additive. Patients must be advised to discontinue salbutamol treatment at least 6 hours before planned anaesthesia with halogenated anaesthetic agents, whenever possible.

Pack size
One Unit Aluminium Aerosol of 200 Metered Doses.

Storage Condition
Store below 30°C. Shelf Life 36 months.

Manufacturer
Laboratorio ALDO-UNIÓN, S.L. Baronesa de Maldá, 73
08950 Esplugues de Llobregat
BARCELONA – SPAIN.

Product Registration Holder
Healol Pharmaceuticals Sdn. Bhd.,
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia.

Date of Revision
September 2024