VENTOLIN ACCUHALER
Proposed Package Insert

VENTOLIN ACCUHALER

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

VENTOLIN ACCUHALER powder for inhalation

COMPOSITION:

Each blister contains salbutamol sulphate equivalent to 200 µg of salbutamol.

Excipients: lactose which contains milk protein.

PHARMACOLOGICAL CLASSIFICATION:

A.10.2.1 Medicines acting on respiratory system. Inhalants

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Salbutamol is a beta-adrenergic stimulant which has a selective action on the receptors in bronchial muscle and, in therapeutic dosage, little or no action on the cardiac receptors.

The action of salbutamol by inhalation is rapid; near maximal bronchodilatation occurring within five minutes.

Pharmacokinetic properties:

Absorption: 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.

Distribution: Salbutamol is bound to plasma proteins to the extent of 10 %.

Metabolism: On reaching the systemic circulation, salbutamol becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged medicine and as the inactive sulphate conjugate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the sulphate conjugate.

Elimination: Salbutamol administered intravenously has a half-life of four to six hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate sulphate conjugate) 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.

INDICATIONS:

VENTOLIN ACCUHALER is indicated for the treatment of reversible airways obstruction in asthma, chronic bronchitis and emphysema.

VENTOLIN ACCUHALER is indicated for the prophylaxis of bronchospasm in exercise induced asthma.

CONTRA-INDICATIONS:

VENTOLIN ACCUHALER is contra-indicated in patients with a history of sensitivity to any of its components.

Inhaled salbutamol preparations are not appropriate for managing premature labour.

VENTOLIN ACCUHALER should not be used for threatened abortion.

VENTOLIN ACCUHALER is contra-indicated in patients with severe milk-protein allergy (see WARNINGS AND SPECIAL PRECAUTIONS).

WARNINGS AND SPECIAL PRECAUTIONS:

VENTOLIN ACCUHALER should be administered cautiously to patients suffering from thyrotoxicosis.

VENTOLIN ACCUHALER should be used with caution in patients with cardiovascular disorders especially ischaemic heart disease, angina pectoris, tachycardia, dysrhythmias and hypertension. VENTOLIN ACCUHALER should be used with caution in patients known to have received other sympathomimetic medicine.

Beta-blocking medicines should not be used in patients who require VENTOLIN ACCUHALER for airflow obstruction.

Increasing use of VENTOLIN ACCUHALER 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 VENTOLIN ACCUHALER failing to give relief for at least 3 hours, the patient should be advised to seek medical advise.

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

In the event of a previously effective dose of VENTOLIN ACCUHALER 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.

Potentially serious hypokalaemia may result from VENTOLIN ACCUHALER therapy.

Particular caution is advised in acute severe asthma, as hypokalaemia 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.

Overdosage may cause cardiac effects. High dosages may increase the risk of serious side effects, including cardiac dysrhythmias. The risk is further aggravated if administered concomitantly with other medicines that cause hypokalaemia and cardiac dysrhythmias or in the presence of hypoxia and acidosis. The maximum dose should not be exceeded.

VENTOLIN ACCUHALER contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine (see CONTRA-INDICATIONS).

INTERACTIONS:

Beta-blocking medicines should not be used in patients who require VENTOLIN ACCUHALER for airflow obstruction.

VENTOLIN ACCUHALER should be used with caution in patients undergoing anaesthesia with halogenated anaesthetics, as ventricular fibrillation may be induced. An increased risk of dysrhythmias may also occur if administered concomitantly with digoxin, quinidine or tricyclic antidepressants. VENTOLIN ACCUHALER should not be given to patients receiving mono-amine oxidase inhibitors or within 14 days of termination of mono-amine oxidase inhibitor therapy.

PREGNANCY AND LACTATION:

Safety during pregnancy and lactation has not been established.

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DOSAGE AND DIRECTIONS FOR USE:

VENTOLIN ACCUHALER is administered by the inhaled route only, to be breathed in through the mouth.

Increasing use of VENTOLIN ACCUHALER may be a sign of worsening asthma. Under these conditions, a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

Relief of acute bronchospasm:

VENTOLIN ACCUHALER use should not exceed four times daily. Reliance on supplementary use or a sudden increase in dose indicates deteriorating asthma (see WARNINGS AND SPECIAL PRECAUTIONS).

Adults:

One VENTOLIN ACCUHALER blister (200 µg) as required.

Children (5 - 12 Years) :

One VENTOLIN ACCUHALER blister (200 µg) as required.

Prevention of allergen or exercise-induced bronchospasm:

Adults:

One VENTOLIN ACCUHALER blister (200 µg) before excercise.

Children (5 - 12 years):

One VENTOLIN ACCUHALER blister (200 µg before excercise.

Chronic therapy:

Adults:

One VENTOLIN ACCUHALER blister (200 µg) four times daily.

Children (5 - 12 years):

One VENTOLIN ACCUHALER blister (200 µg) four times daily.

Elderly:

There is no need to adjust the dose in the elderly.

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. In these patients concomitant glucocorticosteroid therapy should be administered. Failure to respond promptly or fully to VENTOLIN ACCUHALER inhalation signals a need for urgent medical advice and treatment.

SIDE EFFECTS:

Side effects are listed below by system organ class and frequency. Frequencies are defined as: very common ≥ 1/10, common ≥ 1/100 to < 1/10, uncommon ≥ 1/1 000 to < 1/100, rare ≥ 1/10 000 to < 1/1 000 and very rare < 1/10 000 including isolated reports.

Clinical trial data:

Nervous system disorders:

Common: tremor of skeletal muscle (particularly the hands), headache

Cardiac disorders:

Common: tachycardia

Uncommon: palpitations

Gastrointestinal disorders:

Uncommon: mouth and throat irritation

Musculoskeletal and connective tissue disorders:

Uncommon: muscle cramps.

Post-marketing data:

Immune system disorders: anaphylactic reaction (hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse)

Metabolism and nutrition disorders: potentially serious hypokalaemia may occur

Nervous system disorders: hyperactivity, agitation, nervousness, fatigue, fear, restlessness, dizziness, confusion, insomnia

Cardiac disorders: cardiac dysrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

Vascular disorders: peripheral vasodilatation

Respiratory, thoracic and mediastinal disorders: paradoxical bronchospasm

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation of salbutamol or a different fast-acting inhaled bronchodilator. In this instance VENTOLIN ACCUHALER should be discontinued immediately, the patient assessed and if necessary, alternative therapy instituted.

Gastrointestinal disorders: loss of appetite, nausea, vomiting.

Other effects that may occur with sympathomimetic agents include difficulty in micturition, urinary retention, dyspnoea, altered metabolism, sweating and hypersalivation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms and Signs:

The most common signs and symptoms of overdose with VENTOLIN ACCUHALER are beta-agonist pharmacologically-mediated events (refer to SIDE EFFECTS).

Agitation, hallucinations and irritability have been reported.

Hypokalaemia may occur following overdose with VENTOLIN ACCUHALER. Serum potassium levels should be monitored.

Treatment:

Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy.

IDENTIFICATION:

Each blister contains a white powder.

PRESENTATION:

The VENTOLIN ACCUHALER consists of a plastic inhaler device, containing a foil strip with 60 blisters. The device contains a dose counter which shows the number of doses remaining (60 to 1). To show when the last five doses have been reached, the number appears in red.

STORAGE INSTRUCTIONS:

Store at or below 30 °C.

Keep out of reach of children.

REGISTRATION NUMBER:

31/10.2.1/0120

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NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

GlaxoSmithKline South Africa (Pty) Ltd

57 Sloane Street

Bryanston, 2021

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

23 March 2015