PRESCRIBING INFORMATION FOR UAE, KUWAIT, OMAN, BAHRAIN AND QATAR
VENTOLIN DISKUS 200 MICROGRAMS
Microfine Salbutamol (as Sulphate)

Qualitative and Quantitative Composition
VENTOLIN DISKUS is a plastic inhaler device containing a foil strip with 60 regularly spaced blisters each containing a mixture of 200 micrograms of microfine salbutamol (as sulphate) and larger particle lactose.
Excipients with known effect: Contains Lactose monohydrate 12.5 mg/blister.

Pharmaceutical Form
Multi-dose dry powder inhalation device.

Therapeutic Indications
VENTOLIN DISKUS is indicated in adults, adolescents, and children aged 4 to 11 years.
VENTOLIN DISKUS can be used in the management of asthma, bronchospasm, and/or reversible airway obstruction.
VENTOLIN DISKUS is particularly suitable for the relief of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).
VENTOLIN DISKUS 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.

Posology and Method of Administration
VENTOLIN DISKUS is for inhalation use only. VENTOLIN DISKUS is suitable for many patients including those who cannot use a metered-dose inhaler successfully.

Adults (including the elderly)
For the relief of acute bronchospasm, 200 micrograms as a single dose. The maximum daily dose is 200 micrograms four times a day.
To prevent allergen- or exercise-induced symptoms, 200 micrograms should be taken 10 to 15 minutes before challenge.

Paediatric Population
Relief of acute bronchospasm
Children aged 4 to 11 years: 200 micrograms as required

Children aged 12 years and over: Dose as per adult population

Prevention of allergen or exercise-induced bronchospasm
Children aged 4 to 11 years: 200 micrograms before challenge or exertion

Children aged 12 years and over: Dose as per adult population

Chronic therapy
Children aged 4 to 11 years: 200 micrograms four times a day

On-demand use of VENTOLIN DISKUS should not exceed four times daily. Reliance on such frequent supplementary use, or a sudden increase in dose, indicates poorly controlled or deteriorating asthma

Children aged 12 years and over: Dose as per adult population

Contraindications
Hypersensitivity to the active substance or any of the excipients.
Non-i.v. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.
VENTOLIN DISKUS is contraindicated in patients with severe milk-protein allergy.

Special Warnings and Precautions for Use
Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death. Physicians should consider using the maximum recommended dose of inhaled corticosteroid and/or oral corticosteroid therapy in these patients.
The dosage or frequency of administration should only be increased on medical advice.
Increasing use of bronchodilators, in particular, short-acting inhaled β_2-agonists to relieve symptoms, indicates deterioration of asthma control. The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required. In this situation, the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid).

Severe exacerbations of asthma must be treated in a normal way.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic 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 dyspnoea and chest pain, as they may be of either respiratory or cardiac origin. Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis. Potentially serious hypokalaemia may result from β_2-agonist therapy, mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids, and diuretics. Serum potassium levels should be monitored in such situations. As with 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. VENTOLIN DISKUS should be discontinued immediately, the patient assessed, and if necessary a different fast-acting bronchodilator instituted for ongoing use.

Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

Interaction with Other Medicinal Products and Other Forms of Interaction
Salbutamol and non-selective β-blocking drugs such as propranolol, should not usually be prescribed together.

Fertility, Pregnancy, and Lactation
Pregnancy
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. As with the majority of drugs, there is little published evidence of the safety of salbutamol in the early stages of human pregnancy, but in animal studies, there was evidence of some harmful effects on the foetus at very high dose levels.
Breast-feeding
As salbutamol is probably secreted in breast milk, its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.
Fertility
There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals.

Effects on Ability to Drive and Use Machines
None reported.

Undesirable Effects
Adverse events are listed below by system organ class and frequency. Frequencies are defined as: (very common ≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare, very rare, and unknown events were generally determined from spontaneous data.
Immune System Disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension, and collapse
Metabolism and Nutrition Disorders
Rare: Hypokalaemia
Potentially serious hypokalaemia may result from β_2-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 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

Overdose
The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity, and metabolic effects including hypokalaemia.

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored. Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Pharmacological Properties

Pharmacodynamic properties

Pharmacotherapeutic group: Adrenergics, inhalants. Selective beta-2-adrenoceptor agonists.
ATC code: R03AC02

Salbutamol is a selective β_2-adrenoceptor agonist. At therapeutic doses, it acts on the β_2-adrenoceptors of bronchial muscle providing Short-acting (4-6 hours) bronchodilation with a fast onset (within 5 minutes) in reversible airway obstruction.

Pharmacokinetic properties

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-sulfate (phenolic sulfate) which is also excreted primarily in the urine. The faeces are a minor route of excretion.

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 sulfate.

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. Most 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%.

Preclinical safety data

In common with other potent selective β_2-receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate at 2.5mg/kg, 4 times the maximum human oral 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 foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50 mg/kg/day, 78 times the maximum human oral dose.

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 the number of weanlings surviving to day 21 post-partum at 50 mg/kg/day, there were no adverse effects on fertility, embryofoetal development, litter size, birth weight, or growth rate.

Pharmaceutical Particulars

List of excipients

Lactose (which contains milk protein)

Incompatibilities

None reported

Shelf life

24 months

Special precautions for storage

Store below 30°C (86°F). Store in a dry place

Nature and Contents of Container

The powder mix of salbutamol (as sulphate) and lactose is filled into a blister strip consisting of a formed base foil with a peelable foil laminate lid. The foil strip is contained within the Diskus device.

Special precautions for disposal

The powdered medicine is inhaled through the mouth into the lungs.
The Diskus device contains the medicine in individual blisters which are opened as the device is manipulated.
For detailed instructions for use refer to the Patient Information Leaflet in every pack.

Marketing Authorisation Holder

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06/12/1995 / 27/04/2001

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16/12/2019

Reporting of side effects

Detailed information on this medicinal product can be requested Via: gcc.medinfo@gsk.com To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com All Quality complaints should be reported to the LOC Quality department mailbox Gulf.ProductQualityComplaints@gsk.com

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