SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ventolin Accuhaler 200 micrograms

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ventolin Accuhaler 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 sulfate) and larger particle lactose.

Excipients with known effect: Contains Lactose monohydrate (which contains milk protein) 12.5 mg/blister (see section 4.4).

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Multi-dose dry powder inhalation device.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ventolin Accuhaler is indicated in adults, adolescents and children aged 4 to 11 years.

Ventolin Accuhaler can be used in the management of asthma, bronchospasm and/or reversible airways obstruction.

Ventolin Accuhaler 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).

In asthma, short acting beta-2 agonists including Salbutamol Accuhaler should not be the main or only treatment. It is recommended that short acting beta-2 agonists should be prescribed with concomitant inhaled corticosteroid (anti-inflammatory).

4.2 Posology and method of administration

Posology
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 10-15 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 Accuhaler should not exceed four times daily. Reliance on such frequent supplementary use, or a sudden increase in dose, indicates poorly controlled or deteriorating asthma (see section 4.4).

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

Method of Administration
Ventolin Accuhaler is for inhalation use only. Ventolin Accuhaler is suitable for many patients including those who cannot use a metered-dose inhaler successfully.

Salbutamol inhaled formulations are administered by the inhaled route only, to be breathed in through the mouth.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

Non-IV formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.

Ventolin Accuhaler is contraindicated in patients with severe milk-protein allergy.

4.4 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.

Patients who are prescribed regular anti-inflammatory therapy (*e.g.*, inhaled corticosteroids) should be advised to continue taking their anti-inflammatory medication even when symptoms decrease, and they do not require Ventolin Accuhaler.
Increasing use of bronchodilators, in particular short-acting inhaled β_2-agonists to relieve symptoms, indicates deterioration of asthma control, and patients should be warned to seek medical advice as soon as possible. Under these conditions, the patient's therapy plan should be reassessed.

Overuse of short-acting beta-agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control, leading to an increased risk of severe asthma exacerbations and mortality.

Patients who take more than twice a week “as needed” salbutamol, not counting prophylactic use prior to exercise, should be re-evaluated (i.e., daytime symptoms, night-time awakening, and activity limitation due to asthma) for proper treatment adjustment as these patients are at risk for overuse of salbutamol.

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.

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 the event of a previously effective dose of inhaled salbutamol now failing to give relief for a duration of at least three hours following administration, the patient should be advised to promptly seek medical advice in order that any necessary additional steps may be taken. 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 the 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.

Increasing use of β_2-agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient’s therapy plan may be required and concomitant corticosteroid 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.

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 Accuhaler should be discontinued immediately, the patient assessed, and if necessary a different fast-acting bronchodilator instituted for on-going use.

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

4.5 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.

4.6 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, and 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 (see section 5.3).

4.7 Effects on ability to drive and use machines

None reported.

4.8 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 beta$_2$ 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* (see section 4.4)

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.

* reported spontaneously in post-marketing data therefore frequency regarded as unknown

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 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 (see sections 4.4 and 4.8).

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Andrenergics, inhalants. Selective beta-2-andrenoreceptor 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, with little or no action on the β_1-adrenoceptors of cardiac muscle.

Salbutamol provides short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

5.2 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 sulfate. Both unchanged drug and conjugate are excreted primarily in the urine. Almost all 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%.

5.3 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 fetuses were found to have cleft palate at 2.5 mg/kg, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50 mg/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. A

reproductive study in rabbits revealed cranial malformations in 37% of fetuses 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 number of weanlings surviving to day 21 post partum at 50 mg/kg/day, there were no adverse effects on fertility, embryofetal development, litter size, birth weight or growth rate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose (which contains milk protein)

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 30°C. Keep in the original container.

6.5 Nature and contents of container

The powder mix of salbutamol (as sulfate) 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 Accuhaler device.

6.6 Special precautions for disposal

The powdered medicine is inhaled through the mouth into the lungs.

The Accuhaler 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.

7 MARKETING AUTHORISATION HOLDER

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