SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Salbutamol 5mg/2.5ml Nebuliser Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 5 mg salbutamol (as sulfate).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser Solution

A clear, colourless to pale yellow solution in a clear, plastic single dose ampoule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Salbutamol Nebuliser Solution are indicated in adults, adolescents and children aged 4 years and above, see section 4.2.

Salbutamol Nebuliser Solution is indicated for use in the routine management of chronic bronchospasm unresponsive to conventional therapy and the treatment of acute severe asthma.

4.2. Posology and method of administration

Salbutamol Nebuliser Solution is for inhalation use only, to be breathed in through the mouth, under the direction of a physician, using a suitable nebuliser, via a face mask or T piece or via an endotracheal tube.

To open the plastic ampoule, take a strip of ampoules from the foil pack, remove one ampoule, replacing the rest back in the foil pack, and replace the foil pack back in the carton. Hold the ampoule upright and open it by twisting off the top. Squeeze the liquid into the solution holder of the machine.

Private purchase of nebuliser devices for use at home to deliver rescue therapy for the acute treatment of asthma in children and adolescents is not recommended.

Only specialists in respiratory medicine should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents.

Children should be trained in the correct use of their device to deliver rescue therapy and use should be supervised by a responsible adult.

Urgent medical assistance should be sought if worsening asthma symptoms are not relieved by rescue medicines, even if there is short-term recovery following use of prescribed nebulised medication.

The solution should not be injected or swallowed.

Dosage:

Adults *(including the elderly)*
2.5 mg to 5 mg salbutamol up to four times a day. Up to 40 mg per day can be given under strict medical supervision in hospital.

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

Children aged 4 to 11 years: 2.5mg to 5mg up to four times a day.

Other pharmaceutical forms may be more appropriate for administration in children under 4 years old.

Infants under 18 months old: Clinical efficacy of nebulised salbutamol in infants under 18 months is uncertain. As transient hypoxia may occur supplemental oxygen therapy should be considered.

Salbutamol Nebuliser Solution is designed to be used undiluted. However, if prolonged delivery time (more than 10 minutes) is required, then dilution with Sodium Chloride Solution (0.9%w/v) for Nebulisation or sterile sodium chloride injection (normal saline) may be required.

4.3 Contraindications

Hypersensitivity to the active substance salbutamol 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.

4.4 Special warnings and precautions for use

Salbutamol Nebuliser Solution must only be used by inhalation, to be breathed in through the mouth and must not be injected or swallowed.

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 receiving treatment at home should seek medical advice if treatment with Salbutamol Nebuliser Solution becomes less effective. The dosage or frequency of administration should only be increased on medical advice.

Patients being treated with Salbutamol Nebuliser Solution may also be receiving other dosage forms of short-acting inhaled bronchodilators to relieve symptoms.

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 Salbutamol Nebuliser Solution.

Increasing use of bronchodilators, in particular short-acting inhaled β2-agonists to relieve symptoms, indicates deterioration of asthma control, and patients should be warned to seek medical advice as soon as possible. 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 patients 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).
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.

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

Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis.

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 ischemia associated with 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 dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Salbutamol Nebuliser Solution should be used with care in patients known to have received large doses of other sympathomimetic drugs.

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.

In common with other β-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Lactic acidosis has been reported in association with high therapeutic doses of intravenous and nebulised short-acting beta-agonist therapy, mainly in patients being treated for an acute asthma exacerbation (see Section 4.8). Increase in lactate levels may lead to dyspnoea and compensatory hyperventilation, which could be misinterpreted as a sign of asthma treatment failure and lead to inappropriate intensification of short-acting beta-agonist treatment. It is therefore recommended that patients are monitored for the development of elevated serum lactate and consequent metabolic acidosis in this setting.

A small number of cases of acute angle-closure glaucoma have been reported in patients treated with a combination of nebulised salbutamol and ipratropium bromide. A combination of nebulised salbutamol with nebulised anticholinergics should therefore be used cautiously. Patients should receive adequate instruction in correct administration and be warned not to let the solution or mist enter the eye.

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. Salbutamol Nebuliser Solution should be discontinued, and if necessary a different fast-acting bronchodilator instituted for on-going use.

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

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 known

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). Very common and common events were generally determined from clinical trial data. Rare, very rare and unknown events were generally determined from spontaneous data.

Organ System	**Frequency**	**Adverse drug reaction**
Immune system disorders	Very rare (including isolated cases) (<1/10,000)	Hypersensitivity reactions (including angioedema, urticaria, bronchospasm, hypotension and collapse)

Metabolism and nutrition disorders	Rare (>1/10,000, <1/1,000)	Hypokalaemia (potentially serious hypokalaemia may result from β2-agonist therapy)
	Not known (frequency cannot be estimated from the available data)	Lactic acidosis (see section 4.4)
Nervous system disorders	Common (>1/100, <1/10)	Tremor, headache
	Very rare (including isolated cases) (<1/10,000)	Hyperactivity
	Not known (frequency cannot be estimated from the available data)	Sleep disturbances
Cardiac disorders	Common (>1/100, <1/10)	Tachycardia
	Uncommon (>1/1,000, <1/100)	Palpitations
	Very rare (<1/10,000)	Cardiac arrhythmia (atrial fibrillation, supraventricular tachycardia, extrasystoles)
	Not known (frequency cannot be estimated from the available data)	Myocardial ischemia* (see section 4.4)
Vascular disorders	Rare (>1/10,000, <1/1,000)	Peripheral vasodilation
Respiratory, thoracic and mediastinal disorders	Very rare (>1/10,000)	Paradoxical bronchospasm
Gastrointestinal disorders	Uncommon (>1/1,000, <1/100)	Mouth and throat irritation
Musculoskeletal and connective tissue disorders	Uncommon (>1/1,000, <1/100)	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 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

Symptoms of an 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 and lactic acidosis (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 β2-agonist providing short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction. At therapeutic doses it acts on the β2-adrenoceptors of bronchial muscle. With its fast onset of action, it is particularly suitable for the management and prevention of attack in asthma.

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. 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%.

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.

5.3. Pre-clinical safety data

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

Sodium chloride

Water for injections

Sulfuric acid for pH adjustment

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

As packaged for sale, 3 years

After opening of foil packaging, 6 months

6.4 Special precautions for storage

Store below 25 ºC. Store in the original packaging.

Ampoules should be opened immediately before use and any solution remaining after use should be discarded.

6.5 Nature and contents of container

Each carton contains 20 or 60 unit dose low density polyethylene ampoules in foil wrapped strips of ten.

6.6 Special precautions for disposal

Salbutamol Nebuliser Solution is designed to be used undiluted. However, for a prolonged delivery time (more than 10 minutes) dilution with sodium chloride solution (0.9%w/v) for nebulisation or sterile sodium chloride injection (normal saline) may be necessary.

7 MARKETING AUTHORISATION HOLDER

Accord-UK Ltd

(Trading style: Accord)

Whiddon Valley

Barnstaple

Devon

EX32 8NS

8 MARKETING AUTHORISATION NUMBER(S)

PL 0142/1219

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/06/2008

10 DATE OF REVISION OF THE TEXT

30/10/2025