Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Salbutamol Nebulizer Solution BP 2.5 mg Respules

2. Qualitative and quantitative composition

Each 2.5 ml Respules contains:

Salbutamol Sulphate BP

Eq. to Salbutamol..... 2.5 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Nebulizer Solution

Clear & colorless solution

4. Clinical particulars

4.1 Therapeutic indications

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

Adults: The usual dose is 2.5 mg given up to three to four times a day by a nebulizer. This may be increased to 5 mg up to three to four times a day if necessary.

However, in domiciliary practice the benefits of increasing the dose of nebulized salbutamol sulphate should be weighed against the risk that a deterioration in the patients underlying condition may be masked. In such circumstances a medical assessment should be considered since alternative therapy may be indicated.

Children: The same dosage as for adults.

Infants: The clinical efficacy of nebulized salbutamol sulphate in infants under 18 months is uncertain. As transient hypoxaemia may occur supplemental oxygen therapy should be considered.

Elderly: The same dosage as for other adults.

Delivery of the aerosol may be by face mask or 'T' piece.
Salbutamol Nebulizer Solution BP 2.5 mg Respules should be used undiluted. However, if a delivery time in excess of 10 minutes is required they should be diluted with Sodium Chloride Injection.

4.3 Contraindications

Hypersensitivity to any of the components of Salbutamol Nebulizer Solution BP 2.5 mg Respules. Although some forms of salbutamol sulphate have been used for the management of premature labour, Salbutamol Nebulizer Solution BP 2.5 mg Respules should not be used for this purpose.

Salbutamol Nebulizer Solution BP 2.5 mg Respules should not be used in threatened abortion.

4.4 Special warnings and precautions for use

The use of nebulized anti-cholinergic agents and nebulized salbutamol sulphate in combination has been reported to precipitate acute angle closure glaucoma. This combination should be used with caution when giving nebulizer therapy to patients with actual or potential glaucoma. The patient should be warned not to allow the solution or mist to enter the eyes.

Salbutamol Nebulizer Solution BP 2.5 mg Respules should be used with caution in patients with thyrotoxicosis or in patients known to have received large doses of other sympathomimetic drugs.

Salbutamol Nebulizer Solution BP 2.5 mg Respules is for use with a nebulizer under the direction of a physician. The solution should not be injected or administrated orally. Patients who use Salbutamol Nebulizer Solution BP 2.5 mg Respules at home should be warned that if their usual dose is less effective or its duration of action reduced them should not increase either the dose or frequency of treatment but should consult their doctor.

As with other inhalation therapy, the potential for paradoxical bronchospasm should be considered. If it occurs the preparation should be discontinued immediately and alternative therapy given. Solutions which are not of neutral pH may rarely cause paradoxical bronchospasm in some patients. Salbutamol and non-selective beta- blocking drugs such as propranolol should not usually be described together. Potential serious hypokalaemia may result from beta2-agonist therapy. Particular caution is advised in acute severe asthma as this effect maybe potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

4.5 Interaction with other medicinal products and other forms of interaction

Beta2-agonists and non-selective beta-blocking drugs as propranolol should not be described together.

4.6 Fertility, pregnancy and lactation

Pregnancy: Administration of drug during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. Salbutamol has been in widespread use for many years in human beings without

apparent ill consequence; this includes its well-established use in the management of premature labour. However, as with the majority of drugs, there is little published evidence of its safety in early stages of human pregnancy but in animal studies there was evidence of some harmful effects on the foetus at high dose levels.

Lactation: 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.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

A small increase in heart rate may occur in patients who inhale large doses of salbutamol sulphate. This is not usually accompanied by any changes in the electrocardiogram.

Cardiac arrhythmias have been reported in association with beta2-agonists, usually in susceptible patients.

Other side effects which occur with very high doses of salbutamol sulphate by inhalation are peripheral vasodilation and fine tremor of skeletal muscle.

Headaches have been rarely reported. They usually disappear with continued treatment. There have been rare reports of transient muscle cramps.

Hypersensitivity reactions including angioedema and urticaria, bronchospasm, hypotension and collapse have been reported very rarely.

Potentially serious hypokalaemia may result from beta2-agonists therapy.

As with other beta2 agonists hyperactivity in children has been reported rarely

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

The most significant symptom of a large over dosage would be a reflex tachycardia. The recommended antidote to over dosage with salbutamol sulphate is a cardio selective beta blocking agent. However, all beta blocking agents should be used with caution in patients with a history of bronchospasm.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic propertiesATC code: R03ACO2

Therapeutic group: Bronchodilators

Salbutamol is a direct acting sympathomimetic agent with predominantly beta-adrenergic activity and a selective action on beta2-receptors. It is used as a bronchodilator in the treatment of asthma.

5.2 Pharmacokinetic properties

Salbutamol does not appear to be metabolized in the lung therefore its ultimate metabolism and excretion following inhalation depends upon the delivery method used, which is determined by the proportion of drug inhaled relative to the proportion inadvertently swallowed.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6.Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride
Disodium Edetate
Sodium Citrate
Citric Acid
Water For Injections

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30^0C. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

4 X 5 X 2.5 ml LDPE Respules packed in unit carton along with leaflet

6.6 Special precautions for disposal and other handling

The nebulized solution may be inhaled through a face mask, T-piece or via an endotracheal tube. Intermittent positive pressure ventilation (IPPV) may be used but is rarely necessary. When there is a risk of anoxia through hypoventilation, oxygen should be added to the inspired air.

As many nebulizers operate on a continuous flow basis, it is likely that some nebulized drug will be released into the local environment. Salbutamol Nebulizer

Solution BP 2.5 mg Respules should therefore be administered in a well-ventilated room, particularly in hospitals when several patients may be using nebulizers at the same time.

Dilution: Salbutamol Nebulizer Solution BP 2.5 mg Respules may be diluted with sterile normal saline. Solutions in nebulizers should be replaced daily.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder

Name: AXA Parenterals Ltd.

Address: Plot No. 936, 937 & 939, Vill. Kishanpur, Jamalpur, Roorkee-247667, Distt. Haridwar (Uttarakhand)

Country: India

Manufacturing site addresses

Name: AXA Parenterals Ltd.

Address: Plot No. 936, 937 & 939, Vill. Kishanpur, Jamalpur, Roorkee-247667, Distt. Haridwar (Uttarakhand)

Country: India

8. Marketing authorization number

H2024/CTD7431/14600

9. Date of first registration

14/02/2024

10. Date of revision of the text

November 2024