Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Salbutamol Oral Solution BP 2 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Salbutamol Sulfate BP

eq. to Salbutamol 2 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Liquid

Pink Coloured Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Salbutamol is indicated in adults, adolescents and children aged 2 to 12 years. Salbutamol is a selective β_2-agonist broncodilator which provides short acting bronchodilation in reversible airways obstruction. Salbutamol is used to rapidly treat asthma, bronchospasm and reversible airways obstruction by widening the airways of the lungs.

4.2 Posology and Method of administration

Route of Administration: Oral

The usual adult dose is (4mg) two 5 ml spoonfuls (10ml), 3 or 4 times per day which may be increased to a maximum of (8mg) four 5 ml spoonfuls (20ml), 3 or 4 times per day. The minimum starting dose is (2mg) one 5 ml spoonful (5ml), 3 or 4 times per day.

In elderly patients and patients who are unusually sensitive to this class of medicine treatment may be initiated with (2mg) one 5 ml spoonful (5ml), 3 or 4 times per day.

Paediatric population

2- 6 years: the minimum starting dose is 1mg as 2.5 ml of syrup three times daily. This may be increased to 2mg as 5 ml of syrup three or four times daily.

6 – 12 years: the minimum starting dose is 2 mg as 5 ml of syrup three times daily. This may be increased to four times daily.

Over 12 years: the minimum starting dose is 2mg three times daily given as 5 ml syrup. This

may be increased to 4 mg as 10 ml syrup three or four times daily.

4.3 Contraindications

- Should not be used in patients hypersensitive to any of the product ingredients.

- Should not be used for threatened abortion during the first or second trimester of pregnancy.

4.4 Special warnings and precautions for use

Patients should be warned that if either the usual relief is diminished or the usual duration of action is reduced, they should not increase the dose or its frequency of administration, but should seek medical advice. Salbutamol causes peripheral vasodilation which may result in reflex tachycardia and increased cardiac output.

Caution should be used in patients suffering from angina, severe tachycardia or thyrotoxicosis.

Caution should be exercised in its use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

Salbutamol should not cause difficulty in micturition (urination) because unlike sympathomimetic drugs such as ephedrine, it does not stimulate α-adrenoceptors. However, there have been reports of difficulty in micturition in patients with prostatic enlargement.

Salbutamol should only be used during pregnancy if considered essential by the physician.

Use with caution in diabetic patients as this product may cause an increase in blood sugar levels. The development of ketoacidosis has been reported as diabetic patients may be unable to compensate for the increase in blood glucose. This effect can be exaggerated by concurrent administration of corticosteroids.

4.5 Interaction with other medicinal products and other forms of interact.

- Caution should be exercised during use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.
- The effects of this product may be altered by guanethidine, reserpine, methyldopa, tricyclic antidepressants.
- Salbutamol oral preparations and beta-blocking drugs, such as propranolol should not usually be prescribed together.
- Salbutamol is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOI's).

4.6 Fertility, Pregnancy and Lactation

Salbutamol should only be used in pregnancy and lactation if considered essential by the physician.

Salbutamol should only be used during pregnancy/lactation if the expected benefits to the mother are greater than any potential risks to the foetus/neonate.

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

The most common side effect of Salbutamol is fine tremor of the hands, which may interfere with precise manual work. Tension, restlessness and a rapid heart beat may also occur. There have been very rare reports of muscle cramps. Hypersensitivity reactions such as angiodema, urticaria, bronchospasm, hypotension and collapse have rarely been reported. Potentially serious hypokalaemia may result from β_2-agonist therapy. Occasional headaches have also been reported. As with other drugs in this class rare reports of hyperactivity in children have been reported.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

The preferred antidote for overdose with salbutamol sulphate is a cardioselective beta-blocking agent, which should be used with caution in patients with a history of bronchospasm. Salbutamol overdose may lead to Hypokalaemia (abnormally low potassium concentration in the blood). Serum potassium levels should therefore be monitored.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

As a beta-adrenergic stimulant for relief of bronchospasm such as occurs with asthma, bronchitis, emphysema. It has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

5.2 Pharmacokinetic properties

Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. After multiple oral doses of salbutamol 4mg four times a day, steady-state plasma concentrations are obtained after 3 days. About half is excreted in the urine as an inactive sulphate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%.

5.3 Preclinical safety data

None stated.

6.0 Pharmaceutical particulars

6.1 List of excipients

Bronopol, Aspartame, Colour Carmosine supra, Citric Acid Monohydrate, Glycerol, Propylene Glycol, Liquid Sorbitol (Non-crystallizing), Flavour Pine apple (Liquid), Purified water.

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

100 ml Amber Coloured PET Bottle with ROPP Cap

6.6 Special precautions for disposal and other handling

None reported

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 08562/08268/VAR/2023

9. Date of first authorisation/renewal of the authorisation

Apr 5, 2023

10. Date of revision of the text

August 2023