Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Salbutamol Tablets BP 4 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Salbutamol Sulfate BP

Eq. to Salbutamol 4 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets

White to off White, round, flat, uncoated tablets with beveled edges and having a score line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Salbutamol tablets are indicated for the relief of bronchospasm such as occurs with asthma, bronchitis and emphysema.

4.2 Posology and Method of administration

Oral: route of administration

Salbutamol has duration of action of 4 to 6 hours in most patients.

Increasing use of beta-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 gluco-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.

Adults:- The usual total daily dose is 12 to 34 mg in three or four divided doses.

In the management of premature labour, after uterine contractions have been controlled by intravenous infusion of Salbutamol and the infusion has been withdrawn, maintenance therapy can be continued with oral Salbutamol. The usual dosage is 4mg, three or four times daily.

Children:-

2 - 6 years: The usual total daily dose is 3 to 8mg in three or four divided doses.

6 - 12 years: The usual total daily dose is 6 to 8mg daily in divided doses.

Over 12 years: The usual total daily dose is 6 to 16mg daily in divided doses.

Special patient groups:

In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 4 mg salbutamol three or four times per day.

4.3 Contraindications

Salbutamol tablets are contraindicated in patients with a history of hypersensitivity to sympathomimetic or any component of the preparation.

Although salbutamol tablets are used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy, salbutamol presentations should not be used for threatened abortion.

Salbutamol should not be used as a tocolytic agent in patients with pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease.

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.

Salbutamol and non-selective beta-blocking drugs, such as Propranolol, should not usually be prescribed together.

- Salbutamol is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs), however the effects of salbutamol may be altered by guanethidine, reserpine, methyldopa and tricyclic antidepressants.

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

4.6 Fertility, Pregnancy and Lactation

Pregnancy

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

Lactation

As Salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk.

It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

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

Very common: Tremor.

Common: Headache.

Very rare: Hyperactivity.

Cardiac disorders

Common: Tachycardia, palpitations Uncommon: (Obstetric indications) myocardial ischaemia (In the management of pre-term labour with salbutamol injection/solution for infusion.)

Unknown: (Respiratory indications) myocardial ischaemia (Reported spontaneously in post-marketing data therefore regarded as unknown)

Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorders:

Rare: Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders

Common: Muscle cramps.

Very rare: Feeling of muscle tension.

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

Symptoms and Signs

The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events.

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

Treatment

Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy such as cardio-selective beta-blocking agents in patients presenting with cardiac symptoms (e.g. tachycardia, palpitations). Beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: beta-2 adrenoceptor agonist

Mechanism of action

Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle, with little or no action on the beta-1 adrenoceptors of the heart. It is suitable for the management and prevention of attack in asthma.

5.2 Pharmacokinetic properties

The majority 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 oral administration, salbutamol 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. The bioavailability of orally administered salbutamol is about 50%.

5.3 Preclinical safety data

None reported.

6.0 Pharmaceutical particulars

6.1 List of excipients

Maize Starch , Lactose, Microcrystalline Cellulose, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Purified talc, Magnesium Stearate, Sodium Starch Glycolate (Type A) , Colloidal Anhydrous Silica ,Purified water.

* Lost during processing

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30^0C in a dry place. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

10 Tablets packed in Blister aluminium foil and clear PVC film and such 10 blisters are further packed in unit carton along with leaflet.

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: 05211/3487/NMR/2017

9. Date of first authorisation/renewal of the authorisation

July 23, 2020

10. Date of revision of the text

August 2023