PACKAGE INSERT TEMPLATE FOR SALBUTAMOL TABLET & SALBUTAMOL SYRUP

Brand or Product Name
[Product name] Tablet 2mg
[Product name] Tablet 4mg
[Product name] Syrup 2mg/5ml

Name and Strength of Active Substance(s)
[Tablet]
Salbutamol sulphate ….mg equivalent to salbutamol 2mg
Salbutamol sulphate ….mg equivalent to salbutamol 4mg

[Syrup]
Salbutamol sulphate ….mg equivalent to salbutamol 2mg/5ml

Product Description
[Visual description of the appearance of the product (eg colour, markings etc)]
eg Tablet - White, circular flat beveled edge film-coated tablets marked '100' on one side
Syrup - Clear, orange-colored viscous syrup with the odour and flavor of oranges and sweet taste

Pharmacodynamics

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. It is suitable for the management and prevention of attack in asthma.

Pharmacokinetics

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-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. 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%.

Indication

Relief of bronchial asthma of all types, chronic bronchitis and emphysema.

Salbutamol tablet is indicated in the management of uncomplicated premature labour during third trimester of pregnancy following the control of uterine contractions with parenteral salbutamol.

Recommended Dosage

Salbutamol has duration of action of 4 to 6 hours in most patients. 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 glucocorticosteroid 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 effective dose is 4mg three or four times per day. If adequate bronchodilatation is not obtained,each single dose may be gradually increased to as much as 8mg.

However, it has been established that some patients obtain adequate relief with 2mg three or four times daily.

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

The following doses should be administered three or four times daily:
2-6 years: 1 to 2 mg
6-12 years: 2mg
Over 12 years: 2 - 4mg

Salbutamol Syrup is suitable oral therapy for children or those adults who prefer liquid medicines.

Special patient group

In elderly patients or in those known to be unusually sensitive to β-adrenergic stimulant drugs, it is advisable to initiate treatment with 2mg three or four times per day.

Mode of Administration
Oral

Contraindications

Salbutamol preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

Although intravenous salbutamol and occasionally 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 preparations should not be used for threatened abortion.

Warnings and Precautions

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting inhaled β_2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient''s therapy plan should be reassessed. 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.

Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol should be administered cautiously to patients with thyrotoxicosis.

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 concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

In common with other β.adrenoceptor agonists, salbutamol can induce reversible metabolic changes, for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Tocolysis: Serious adverse reactions including death have been reported of salbutamol to women in labor. In the mother, these include increased heart rate, transient hyperglycaemia,

hypokalaemia, cardiac arrhythmias, pulmonary oedema and myocardial ischaemia. Increased fetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration.

As maternal pulmonary oedema and myocardial ischaemia have been reported during or following treatment of premature labour with ß2 agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG should be monitored. If signs of pulmonary oedema or myocardial ischaemia develop, discontinuation of treatment should be considered.

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 oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in those patients.

Effect on ability to drive and use machines – none known

Interactions with Other Medicaments

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

Concomitant use of salbutamol and tricyclic antidepressants or monoamine oxidase inhibitors may cause a potentiation of the vascular effects of Salbutamol. Salbutamol is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

Statement on Usage During Pregnancy and Lactation

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 its safety 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.

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.

Adverse Effects / Undesirable Effects

Immune system disorders
Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse

Metabolism and nutrition disorders
Hypokalaemia.

Nervous system disorders
Tremor, headache, hyperactivity

Cardiac disorders
Tachycardia, palpitations, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Vascular disorders
Peripheral vasodilatation.

Musculoskeletal and connective tissue disorders
Muscle cramps, feeling of muscle tension.

Overdose and Treatment

Overdosage symptoms are those of excessive β-stimulation, e.g. seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue and insomnia. Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

Treatment consists of discontinuation of salbutamol together with appropriate symptomatic therapy. Administer a cardioselective β-adrenergic blocker (e.g.acebutalol, atenolol, metoprolol), if necessary for cardiac arrhythmias. However, β -adrenergic blocker should be used with caution because it could induce severe bronchospasm.

Storage Conditions
[eg Store below ….°C]

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]

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