Further information can be obtained from your doctor or pharmacist.

ROYCE®

Product holder / Manufactured by:
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ROYCE®

Salbutamol Tablet 2mg

(Salbutamol Sulphate - Sympathomimetics)

Presentation:
A white to off white coloured, round, flat face, bevel edge tablet with a break line on one side and plain on the other side.

Content:
Each tablet contains:
Salbutamol Sulphate (equivalent to Salbutamol 2mg).

Indication:
Salbutamol is a beta-adrenergic stimulant which has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors. It is used to treat lung diseases such as bronchial asthma, chronic bronchitis and emphysema. It relieves wheezing, shortness or breath and troubled breathing.

Dosage and Administration:
Salbutamol tablets must be swallowed whole with a glass of water and not chewed or crushed.
To be taken 3 or 4 times daily.
Adults and children over 12 years : one to two tablets.
Children: 2 to 6 years - half to one tablet.
6 to 12 years - one tablet.
Over 12 years - one to two tablets.
As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical device.

Pharmacological Information:
A direct acting sympathomimetic amine. Acts relatively selectively on beta-2 adrenergic receptors in the lungs to relax bronchial smooth muscle, thereby relieving bronchospasm and reducing airway resistance.Also, relaxes smooth muscle of the uterus and vascular supply to the skeletal. These actions are believed to result from increased production of cyclic adenosine 3', 5'-monophosphate (cyclic 3', 5'-AMP) caused by activation of the enzyme adenyl cyclase.

Salbutamol is readily absorbed from the gastro-intestinal tract and unlike isoprenaline, is not subject to sulphate conjugation in the gut. It is subject to first-pass metabolism in the liver, about a half is excreted in the urine as an inactive sulphate conjugate, following oral administration (the rest being unchanged Salbutamol), whereas less than a third is excreted as the conjugate following intravenous administration. Salbutamol does not appear to be metabolised in the lung, therefore its behavior following inhalation depends upon the delivery method used, which determines the proportion of inhaled Salbutamol relative to the proportion of inhaled Salbutamol, relative to the proportion inadvertently swallowed. The plasma half-life of Salbutamol has been estimated to range from 2 to as much as 7 hours. In general the shorter value have followed intravenous administration, the intermediate values oral administration and the longer values aerosol inhalation. It has been suggested that the slightly extended half-life following aerosol inhalation. It has been suggested that the slightly extended half-life following inhalation may reflect slow removal of active drug from the lungs.

Contraindication:
Salbutamol should not be used for threatened abortion during the first or second trimester of pregnancy. Salbutamol tablets should not be taken together with beta-blocking drugs, such as propranolol. It is also contraindicated with monoamine oxidase inhibitor, tricyclic antidepressants other sympathomimetics and xanthines.

Patients hypersensitive to other sympathomimetics(e.g. amphetamines,ephedrine, epinephrine, isoproterenol, metaproterenol norepinephrine,phenylephrine,phenylpropanolamine, pseudoephedrine terbutaline) may be hypersensitive to this medications. Patients who have ever had unusual or allergic reaction to Salbutamol preparation should not take Salbutamol tablet.

Warning and Precautions:
Care in patients with cardiovascular disorders, including coronary insufficiency and hypertension, in patients with hyperthyroidism or diabetes mellitus, in patients who are usually responsive to sympathomimetic amines and in patients who are treated with monoamine oxidase inhibitors or tricyclic antidepressants. Salbutamol should be administered cautiously to patient suffering from thyrotoxicosis.

As maternal pulmonary oedema and myocardial ischaemia have been reported during or following premature labour in patients receiving beta2-agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG monitoring. If signs of pulmonary oedema and myocardial ischaemia develop, discontinuation of treatment should be considered.

Due to the risk of pulmonary oedema and myocardial ischaemia that has been observed during the use of beta2-agonists in the treatment of premature labour, before these products are given to any patient with known heart disease, an adequate assessment of the patients's cardiovascular status should be made by a physician experienced in cardiology.

Tocolysis: Serious adverse reactions including death have been reported after administration of terbutaline/ 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.

Interactions With Other Medicaments:
Salbutamol and nonselective β-blocking drugs, e.g. propranolol should not be prescribed together. Adverse metabolic effects of high dose of Salbutamol may be exacerbated by concomitant administration of high doses of corticosteroids, therefore patients should not be administrated together with the above drugs. Propanolol and other beta-adrenoceptor blocking agents antagonize the effects of Salbutamol.

Hypokalaemia associated with high doses of Salbutamol may result in increased susceptibility to digitalis induces cardiac arrhythmias. The effects of Salbutamol, such as hypokalaemia, may also be enhances by concomitant administration of Aminophylline or other xanthines, hypokalaemia can also be enhanced by diuretic therapy.

Pregnancy:
Unnecessary administration to drugs during the first trimester of pregnancy is undesirable.

Side Effects:
The only side effect of significance with oral Salbutamol preparation is a tremor of skeletal muscle which occurs in some patients, usually the hands are most obviously affected. The effect is dose related and is common to all beta-adrenergic stimulants. A few patients feel tense, this is also due to the effects on skeletal muscle and not to direct CNS stimulation. With doses of Salbutamol higher than those recommended or in patients who are unusually sensitive to beta-adrenergic stimulants peripheral vasodilation and a compensatory small increase in heart rate may occur. In addition, Salbutamol like other sympathomimetic agents, can cause adverse reactions such as hypertension, angina, vomiting, vertigo, central stimulation, unusual taste and drying or irritation of the oropharynx. Patient should be aware of the possible signs of overdoes that is chest pain and severe increase in blood pressure. If these symptoms occur consult your doctor immediately.

Symptoms and Treatment of Overdose:
Manifestations of overdosage include anginal pain, hypertension and exaggretion of the effects listed in side effects/adverse reactions.

Dialysis is not appropriate treatment for overdosage of Salbutamol. The judicious use of a cardioselective beta-receptor blocker such as metoprolol tartrate is suggested bearing in mind the danger of including an asthmatic attack.

Storage Condition:
Keep container tightly closed. Store in a dry place (below 30°C). Protect from light.

Pack Size:
Plastic bottle of 30 tablets.
Blister pack of 1 x 10's, 10 x 10's, 50 x 10's and 100 x 10's.

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