Axcel®

SALBUTAMOL - 4 TABLETS

MAL19900030AZ

COMPOSITION:
Each tablet contains
Salbutamol Sulphate
equivalent to Salbutamol 4mg

PRESENTATION:
White, biconvex, round, 8.0mm in diameter tablet with a single score-line on one side and KOTRA logo on the other side.

INDICATIONS:
For the relief of bronchospasm in asthma, chronic bronchitis and other conditions involving airways obstruction.

PHARMACOLOGY:
Mechanism of Action:
Salbutamol is a direct-acting sympathomimetic agent with predominantly beta-adrenergic activity. It acts by combining at beta2-adrenoceptive sites.

Pharmacokinetics:
Salbutamol is readily absorbed from the gastrointestinal tract, its effects occurring within 15 minutes and lasting for about 4 hours. Salbutamol is rapidly excreted in the urine; about 50% of a dose administered by mouth is excreted within 4 hours

DOSAGE AND ADMINISTRATION :
For oral administration only.
Adults : 4mg, 3 or 4 times daily. If adequate bronchodilation is not obtained, each single dose may be gradually increased to as much as 8mg. In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 2mg, 3 or 4 times daily.
Children : The following doses should be administered 3 or 4 times daily.
2 - 6 years : 1 - 2mg
6 - 12 years : 2mg
Over 12 years : 2 - 4mg.
The drug is well tolerated by children so that, if necessary, these doses may be cautiously increased.

CONTRAINDICATION:
Salbutamol is not indicated for the prevention of premature labour associated with toxaemia of pregnancy or antepartum haemorrhage, nor should it be used for threatened abortion during the first and second trimesters of pregnancy. It should not be administered concurrently with beta-blocking drugs, such as propranolol.

WARNING:
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 patients with known heart disease, an adequate assessment of the patients 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.

PRECAUTION:
Caution is required in serious cardiovascular disorders, hyperthyroidism, diabetes mellitus, hypertension and thyrotoxicosis. Prolonged use in high dosage should be avoided as resistance may develop. Unnecessary administration of Salbutamol during the first trimester of pregnancy is undesirable.

SIDE EFFECTS:
The only side effects of significance is a fine tremor of skeletal muscle which occurs in some patients; usually the hands are most obviously affected. This effect is dose related and is common to all beta-adrenergic stimulants. With large doses or in patients who are usually sensitive to beta-adrenergic stimulants peripheral vasodilation and compensatory small increase in heart rate may occur. Occasional headaches have been reported.

OVERDOSAGE AND TREATMENT:
The preferred antidote for overdosage is a cardio selective beta-blocking agent but it should be used with caution in patients with a history of bronchospasm. Most toxic effects subside rapidly when Salbutamol is withdrawn. Tachycardia and cardiac arrhythmias induced by Salbutamol may be diminished by propranolol but it must not be given to asthmatics because of the risk of increasing bronchoconstriction. Practolol may be more suitable in asthmatics. Ventricular arrhythmias might be controlled by the slow intravenous infusion of potassium chloride, 40mmol (40mEq) in 500ml of Dextrose Injection.

STORAGE:
Keep container well closed. Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Available in blister pack of 10 X 10's & 100 x 10's.

Further information can be obtained from pharmacist, physician or the manufacturer.

Product Registration Holder & Manufactured by:
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