Axcel®

DEXCHLORPHENIRAMINE TABLETS

MAL19890140AZ

COMPOSITION:
Each tablet contains
Dexchlorpheniramine Maleate 2mg

PRESENTATION:
Pink, biconvex, round tablets, 8mm in diameter with a single score-line on one side and marked KOTRA on the other side.

INDICATIONS:
For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites, pruritus.

PHARMACOLOGY:
Mechanism of Action:
Dexchlorpheniramine Maleate is an alkylamine derivative with antihistamine and anticholinergic effects. The antihistamine acts by competing with histamine for H1 receptor sites on the effector cells, to the exclusion of agonist molecules, without itself initiating a response. This antagonism is competitive and reversible. It does not prevent the production of histamines.

Pharmacokinetics:
Dexchlorpheniramine Maleate is readily absorbed from the gastrointestinal tract and parenteral sites of administration. Following oral administration, the effects may start within 15 to 30 minutes, reaching peak within 1 hour, and may last about 4 - 6 hours. It is extensively metabolised in the liver, and excreted mainly as metabolites in the urine.

DOSAGE AND ADMINISTRATION:
For oral administration only.
Adult : 1 to 2mg, 4 - 6 hourly, up to a maximum of 12mg / 24 hours.
Children 6 - 12 years : 1mg, 4 - 6 hourly, up to a maximum of 6mg / 24 hours.
Children 2 - 5 years : 0.5mg, 4 - 6 hourly, up to a maximum of 3mg / 24 hours.

CONTRAINDICATIONS:
Contraindicated in patients with known hypersensitivity to antihistamines.

PRECAUTIONS:
May cause drowsiness and hence may impair ability to drive vehicles or operate machinery. MAO inhibitors may prolong some of its actions. Patients should be warned that antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers. Use with caution in patients with narrow angle glaucoma, history of bronchial asthma, hyperthyroidism, cardiovascular disease and prostatic hypertrophy. Use is not recommended in nursing mothers, pregnancy, newborn and premature infants. Safety and efficacy of the drug in children younger than 2 years of age have not been established.

SIDE EFFECTS:
The most common side effect is sedation, varying from drowsiness to deep sleep, and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination. Sedative effects, when they occur, may diminish after a few days. Other side effects include gastrointestinal disturbances, such as nausea, vomiting, diarrhoea or constipation, colic, and epigastric pain. It may also produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest, tingling, heaviness and weakness of the hands. It may potentiate CNS depressants. Large doses may precipitate fits in epileptics.

DRUG INTERACTIONS:
MAO inhibitors may enhance the antimuscarinic effects of dexchlorpheniramine maleate while CNS depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and transquillisers may enhance sedative effects. It is also important to note that dexchlorpheniramine may mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.

OVERDOSAGE AND TREATMENT:
If the drug has been taken recently by mouth, the stomach should be emptied by aspiration and lavage. Emetics are generally of little value. The patient should be kept quiet to minimise the excitation which occurs particularly in children. Convulsions and marked CNS stimulation should preferably be treated with diazepam or phenobarbitone intramuscularly, paraldehyde, thiopentone sodium, and chlorpromazine have also been recommended. Severe hypotension may require fluid replacement, and assisted respiration may be necessary. Forced diuresis is of little value since antihistamines are rapidly metabolised and only traces are recovered in the urine.

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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Date of revision: 11/08/22
Regn - 110822