DEXCHLORAMINE TABLET 2MG

DESCRIPTION

An oval, scored, purplish red tablet marked 'UP'.
Each tablet contains Dexchlorpheniramine maleate 2mg.

INDICATIONS

Dexchlorpheniramine is used for the prophylactic and symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods and sneezing and rhinorrhoea associated with the common cold. It is also indicated for the symptomatic relief of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestations of uticaria and angioedema. In dermatographism and in uticaria associated with transfusions.

PHARMACODYNAMICS

Dexchlorpheniramine is a propylamine derived antihistamine. Its used in the treatment of allergy is due to its action of competing with histamine H1-receptor sites on effector cells. It does not inactivate histamine or prevent its synthesis or release. It thereby prevents, but do not reverse responses mediated by histamine alone. Antihistamines antagonise in varying degrees, most of the pharmacological effects of histamine, including uticaria, pruritus and vasodilation. Dexchlorpheniramine also prevents responses to acetylcholine that are mediated via muscarinic receptors resulting in drying of the nasal mucosa.

PHARMACOKINETICS

Dexchlorpheniramine is the dextrorotatory isomer of chlorpheniramine, which is racemic and has approximately twice the activity. It is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occurring about 2-6 hours after administration by mouth while peak effect occurs at 6 hours after administration. The onset of action of Dexchlorpheniramine is between 15-60 minutes. Bioavailability is low, values of 25%-50% having been reported. About 72% of dexchlorpheniramine in the circulation is bound to plasma proteins. There is wide inter individual variation in the pharmacokinetics of dexchlorpheniramine; values ranging from 14-25 hours have been reported for the half-life. Dexchlorpheniramine is widely distributed in the body, including passage into the CNS. Dexchlorpheniramine maleate is extensively metabolised. Unchanged drug and metabolites are excreted primarily in the urine: excretion is dependent on urinary pH and flow rate. Only trace amounts have been found in the faeces. A duration of action of 4-8 hours has been reported; this is shorter than may be predicted from pharmacokinetic parameters. More rapid and extensive absorption, faster clearance and a shorter half-life have been reported in children.

DOSAGE

Adult
2mg every 4-6 hours as needed.
Usual adult prescribing limit: Up to 12mg daily.
Pediatric
Children 5-12 years: 1mg every 4-6 hours as needed.
Children 2-5 years: 500mcg every 4-6 hours as needed.
Use is not recommended in premature and full term neonates.
Geriatrics
Usual adult dose.
Geriatric patients may be more sensitive to the effects of the usual adult dose.

SIDE EFFECTS

Drowsiness, though less pronounced compared to other antihistamines and thickening of mucous occurs with dexchlorpheniramine. Blurred vision, confusion, difficult or painful urination, dizziness, dry mouth, nose or throat, tachycardia, increased sweating, loss of appetite, paradoxical excitation, photosensitivity, ringing or buzzing in ears, skin rash, stomach upset and constipation have also been reported. These effects are more likely to occur in children and elderly patients. Blood dyscrasias including agranulocytosis, leukopenia, haemolytic anaemia, and thrombocytopenia though rare, have been reported. Other rare side effects include hypotension, headache and paraesthesia.

CONTRAINDICATIONS

Dexchlorpheniramine should not be given to premature infants or neonates: this group of patients has an increased susceptibility to antimuscarinic effects. Dexchlorpheniramine should not be given to patients receiving MAO inhibitor therapy and to patients who have shown a previous hypersensitivity.

PRECAUTIONS

The anticholinergic properties of dexchloramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive or operate machinery. Anticholinergic effects may also precipitate or aggravate urinary retention in patients with bladder neck obstruction, symptomatic prostatic hypertrophy and predisposition to urinary retention. Increased intraocular pressure may precipitate an attack of angle-closure glaucoma. Dexchlorpheniramine should be used with care in patients with pyloroduodenal obstruction, severe cardiovascular disorders and epilepsy. Patients sensitive to one antihistamine may be sensitive to dexchlorpheniramine as well.

Antihistamines may inhibit the cutaneous histamine response, thus producing false-negative results; it is recommended that dexchlorpheniramine be discontinued at least 72 hours before testing begins.

DRUG INTERACTION

Concurrent use with alcohol and CNS depressants such as barbiturates, hypnotics, opioid analgesics, monoamine oxidase (MAO) inhibitors, anxiolytic sedatives and neuroleptics may potentiate the CNS depressant effects. Anticholinergic effects may be potentiated when these medications such as atropine, tricyclic antidepressants and MAO inhibitors are used concurrently with antihistamines. Concurrent use with ototoxic medications such as aminoglycoside antibiotics with antihistamines may mask the symptoms of ototoxicity such as tinnitus, dizziness and vertigo. Additive photosensitising effects may occur with use of these medications with antihistamines.

OVERDOSAGE

Clumsiness or unsteadiness, severe drowsiness, severe dryness of mouth, nose or throat, flushing or redness of face, shortness of breath or troubled breathing are signs and symptoms of anticholinergic effects. Cardiac arrhythmia, CNS stimulation and hypotension are all signs and symptoms of overdosage. Anticholinergic and CNS stimulant effects are more likely to occur in children with overdose while hypotension may also occur in the elderly at usual doses. Overdose may be fatal especially in infants and children. Since there is no specific antidote for overdose with dexchlorpheniramine, treatment is symptomatic and supportive with possible utilisation of the following:

a) Induction of emesis (syrup of ipecac recommended); however, precaution against aspiration is necessary, especially in infants and children.
b) Gastric lavage (isotonic or 0.45% sodium chloride solution) if patient is unable to vomit within 3 hours of ingestion.
c) Saline cathartics (milk of magnesia) and activated charcoal are sometimes used, especially if sustained-release preparations were involved.
d) Vasopressors such as norepinephrine or phenylephrine to treat hypotension; however, epinephrine should not be used since it can paradoxically lower the blood pressure further.
e) Oxygen, external cooling for hyperpyrexia and intravenous fluid.
f) Precaution against use of stimulants (analeptic agents) because they may cause seizures.

Up-to-date information on treatment of overdose can be obtained from The National Poison Centre, Universiti Sains Malaysia.

TOXICOLOGY

Cross sensitivity and/or related problems : Patients sensitive to one of the antihistamines may be sensitive to others.

Carcinogenicity/Tumorigenicity/Mutagenicity : Long term animal studies to evaluate carcinogenic, tumorigenic, or mutagenic potential of most antihistamines have not been performed.

Pregnancy/Reproduction : Studies with dexchlorpheniramine in humans have not been done.
Studies in animals have not shown that dexchlorpheniramine causes adverse effects on the foetus *(FDA Pregnancy Category B)*.

Breast-feeding : First generation antihistamines may inhibit lactation because of their anticholinergic actions. Small amounts of antihistamines are distributed into breast milk; use is not recommended in nursing mothers because of the risk of adverse effects, such as unusual excitement or irritability, in infants.

Pediatrics : Use is not recommended in newborn or premature infants because this age group has an increased susceptibility to anticholinergic effects, such as CNS excitation, and an increased tendency toward convulsions. A paradoxical reaction characterised by hyperexcitability may occur in children taking antihistamines.

Geriatrics : Dizziness, sedation, confusion and hypotension may be more likely to occur in geriatric patients taking antihistamines. A paradoxical reaction characterised by hyperexcitability may occur in geriatric patients taking antihistamines. Geriatric patients are especially susceptible to the anticholinergic side effects, such as dryness of mouth and urinary retention (especially in males) of the antihistamines. If these side effects occur and continue or severe, medication should probably be discontinued.

Dental : Prolonged use of antihistamines may decrease or inhibit salivary flow, this contributing to the development of caries, periodontal disease, oral candidiasis, and discomfort.

PRESENTATION

Blister pack: 100 x 10's

STORAGE CONDITIONS AND USER INSTRUCTIONS

Store in a dry place below 30°C.
Protect from light.
Keep out of reach of children
Jauhkan daripada kanak-kanak
Shelf life: Please refer to outer package
May be taken with food, water or milk
Do not take more medicine than recommended.
May cause drowsiness. If affected, do not drive or operate machinery.
Avoid alcoholic beverages.
Route of administration: Oral

Product Registration Holder:
Duopharma Manufacturing (Bangi) Sdn. Bhd.
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DEXCHLORAMINE

Black 100%

164mm(w) x 180mm (h)