

DAWA-CPM[®]
Chlorpheniramine Maleate
Tablets/syrup

Composition:

Each 5 ml contains Chlorpheniramine maleate BP 2 mg.

Each tablet contains Chlorpheniramine maleate BP 4 mg.

Clinical Pharmacology:

Chlorpheniramine maleate, an alkylamine derivative, is a sedating antihistamine that causes a moderate degree of sedation; it also has antimuscarinic activity. Chlorpheniramine is a racemic mixture; the dextrorotatory isomer, Dex- chlorpheniramine, has approximately twice the activity of chlorpheniramine by weight.

Pharmacokinetics:

Chlorpheniramine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported.

Chlorpheniramine appears to undergo considerable first-pass metabolism. About 70% of Chlorpheniramine in the circulation is bound to plasma proteins. There is wide interindividual variation in the pharmacokinetics of Chlorpheniramine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorpheniramine is widely distributed in the body, and enters the CNS.

Chlorpheniramine maleate is extensively metabolised. Metabolites include desmethyl- and didesmethylchlorpheniramine.

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.

Indications:

Chlorpheniramine maleate is used for the symptomatic relief of allergic conditions including urticaria and angioedema (rhinitis and conjunctivitis), and in pruritic skin disorders.

It is a common ingredient of compound preparations for symptomatic treatment of coughs and the common cold.

Chlorpheniramine may be administered intravenously as an adjunct in the emergency treatment of anaphylactic shock

Dosage and Administration:

Adults: Two 5ml spoonfuls every 4 - 6 hours

Children: 1 - 2 years: Half 5ml spoonful twice daily

Children: 2 - 5 years: Half 5ml spoonful every 4 - 6 hours

Children: 6 - 12 years: One 5ml spoonful every 4 - 6 hours

Adverse Effects:

chlorpheniramine maleate causes CNS depression, with effects varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and incoordination (although paradoxical stimulation may occasionally occur, especially at high doses and in children or the elderly). These sedative effects, when they occur, may diminish after a few days of treatment.

Other adverse effects that are more common with chlorpheniramine maleate include headache, psychomotor impairment, and antimuscarinic effects such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation, and increased gastric reflux. Occasional gastrointestinal adverse effects of chlorpheniramine maleate include nausea, vomiting, diarrhoea, or epigastric pain. Blood disorders, including agranulocytosis, leucopenia, haemolytic anaemia, and thrombocytopenia, although rare, have been reported.

Other adverse effects that have been reported include convulsions, sweating, myalgia, paraesthesias, extrapyramidal effects, tremor, sleep disturbances, depression, confusion, tinnitus, hypotension, and hair loss. Allergies (in the form of rash, urticaria and angio-oedema) have been observed which subside on discontinuation of the use.

Overdosage:

Symptoms and signs:

The estimated lethal dose of chlorpheniramine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment:

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion.)

Treat hypertension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam.

Haemoperfusion may be used in severe cases.

Interactions:

Chlorpheniramine maleate may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic, and antipsychotics.

Chlorpheniramine maleate has an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs).

Chlorpheniramine inhibits phenytoin metabolism and can head to phenytoin toxicity.

Presentation:

Plastic jars containing 1000 tablets. And blister pack of 10 x 10 per unit box.

60 ml and 100 ml amber coloured bottles

Storage:

Store in cool dry place below 30°C, Protect from direct sunlight.

Keep all medicines out of reach of children.

Manufactured By:



DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.