DAWA-CPM®

(Chlorpheniramine **Maleate Tablets/Syrup)**

Composition: Each 5 ml contains Chlorpheniramine maleate BP 2 mg.
Each tablet contains Chlorpheniramine maleate BP 4 mg.

Pharmacology: Chlorphenamine is a potent antihistamine (H_1-antagonist). Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H_1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity. Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

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 didesmethyl Chlorpheniramine. 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:

Oral Administration only.

Do not exceed the stated dose or frequency of dosing. Minimum dosing interval: 4 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 or ½ tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) in any 24 hours.

Adults and children 12 years and over: 1 tablet or two 5ml spoonful's 4 to 6 hourly. Maximum daily dose: 6 tablets (24 mg) in any 24 hours.

Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g., a maximum of 12 mg in any 24 hours).

Not recommended for children below 1 year

Special Populations: Patients with renal or hepatic impairment should seek doctor's advice prior to taking this medicine.

Contraindications: Chlorpheniramine are contra-indicated in patients who are hypersensitive to antihistamines or to any of the tablet ingredients. The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). It is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

Special warnings and precautions for use: Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g., increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion. The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery. Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines. The effects of alcohol may be increased and therefore concurrent use should be avoided. Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interaction with other medicinal products and other forms of interaction: Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, concurrent use of alcohol may have a similar effect therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines. Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity. The anticholinergic effects of chlorphenamine are intensified by MAOIs.

Fertility, pregnancy and lactation: There are no adequate data from the use of chlorphenamine maleate in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician. Chlorphenamine maleate and other antihistamine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

Effects on ability to drive and use machines: The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

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: The estimated lethal dose of chlorphenamine 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 contra-indications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. Diazepam. Haemoperfusion may be used in severe cases. Chlorpheniramine inhibits phenytoin metabolism and can head to phenyfoinfoxility.

Presentation: Blister pack of 10 x 10's in unit box, bulk pack of 1000's in HDPE jars for tablets and 60 ml and 100 ml Amber-coloured bottles for syrup

Storage: Store in a dry place, below 30°C, Protect from direct sunlight. Keep all medicines out of reach of children.

Manufactured By:

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Ref: D-CPM /LL/03/22 Date of issue: September 2022