Chlorpheniramine maleate 4 mg tablets

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NAME OF THE MEDICINAL PRODUCT
Chlorphenamine Maleate 4 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION
Chlorphenamine Maleate BP 4 mg

PHARMACEUTICAL FORM
Tablet

CLINICAL PARTICULARS
Therapeutic indications

The symptomatic control of allergic conditions that respond to antihistamines, including urticaria, hayfever, food allergy, drug and serum reactions, insect bites, vaso-motor rhinitis and angioneurotic oedema.

Posology and method of administration
Adults:
4 mg four to six hourly, max. 24 mg daily.

Children:
Below 1 year - Not recommended
1 to 2 years – 1 mg twice daily
3 to 5 years – 1 mg four to six hourly, max. 6 mg daily.
6 to 12 years – 2 mg four to six hourly, max. 12 mg daily.

Elderly:
Same as in adults but they are prone to confusional psychosis and other neurological anticholinergic effects.

Tablets to be taken by mouth.

Contraindications
Hypersensitivity to antihistamines. Patients on monoamine oxidase inhibitor therapy within the previous 14 day.

Special warnings and precautions for use
Effects of alcohol may be increased.

Use with caution in epilepsy, prostatic hypertrophy, urinary retention, glaucoma, hepatic disease, bronchitis, thyrotoxicosis, raised intra-ocular pressure, severe hypertension or cardiovascular disease and bronchial asthma.

Sedation inappropriate in severe liver disease – avoid use of chlorphenamine as it is a sedating antihistamine.

Children and the elderly are more likely to experience the neurological anticholinergic effects.

Patients with rare hereditary problems of lactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interaction with other medicinal products and other forms of interaction
Alcohol potentiates sedation due to chlorphenamine.
Sedative antihistamines interact with hypnotics and anxiolytics causing potentiation of drowsiness.
The risk of antimuscarinic side effects is increased when antihistamines are given with antimuscarinics.
Antidepressants increase the sedative and antimuscarinic effects of antihistamines.
MAOI inhibitor therapy intensifies the antimuscarinic effects of chlorphenamine.
Chlorphenamine inhibits phenytoin metabolism leading to phenytoin toxicity.
Lopinavir may increase the plasma concentration of chlorphenamine.

Pregnancy and lactation
Safety for use during pregnancy has not been established. Use when clearly needed and when potential benefit outweighs the potential unknown risks to the foetus. Use during the third trimester may result in reactions in the newborn or premature neonates.

Small amounts of antihistamines are excreted in breast milk.

Use by nursing mothers is not recommended because of the risks of adverse effects in the infant. Antihistamines may inhibit lactation.

Effects on ability to drive and use machines
Chlorphenamine causes drowsiness, dizziness, blurred vision and incoordination which can seriously hamper the patient's ability to drive and to use machines. Patients are, therefore, advised not to drive or operate machinery whilst taking Chlorphenamine tablets.

Undesirable effects
Cardiac disorders: rarely palpitation, tachycardia, arrhythmias
Blood and lymphatic system disorders: rarely haemolytic anaemia and other blood dyscrasias. Nervous system disorders: Commonly sedation varying from slight drowsiness to deep sleep. Occasionally headaches and concentration ability impaired. Rarely in-coordination.
Eye disorders: occasionally blurred vision
Ear and labyrinth disorders: rarely tinnitus
Respiratory, thoracic and mediastinal disorders: rarely increased viscosity of bronchial secretions Gastrointestinal disorders: occasionally gastro-intestinal disturbances such as nausea, vomiting, diarrhoea, abdominal pain, dyspepsia and anorexia; dry mouth.
Renal and urinary disorders: occasionally urinary retention
Skin and subcutaneous tissue disorders: rarely hypersensitivity reactions including exfoliative dermatitis, photosensitivity and skin reactions such as urticaria.
Musculoskeletal and connective tissue disorders: rarely twitching and muscular weakness.
Vascular disorders: rarely hypotension.
General disorders and administration site conditions: occasionally lassitude; rarely dizziness, tightness of chest and irritability.
Hepatobiliary disorders: rarely hepatitis, including jaundice.
Psychiatric disorders: rarely depression and nightmares. Paradoxical excitation in children and confusional psychosis in the elderly can occur.

Overdose
The estimated lethal dose of Chlorphenamine is 25-50 mg/kg bodyweight. Symptoms and signs include sedation, paradoxic stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias. Treatment includes gastric lavage or emesis using syrup of ipecac. Following these measures activated charcoal and cathartics may be administered to minimise absorption. Other symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance.

Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with IV diazepam or phenytoin. Haemoperfusion may be used in severe cases.

PHARMACOLOGICAL PROPERTIES
Chlorphenamine Maleate is a phenothiazine derivative with properties of prolonged antihistamine action. It also has some anticholinergic, antiserotoninergic and marked local anaesthetic properties. Chlorphenamine maleate diminishes the main actions of histamine in the body, probably by occupying the receptor sites in the effector cells to the exclusion of histamine, but does not prevent the production of histamine.

Chlorphenamine Maleate is a H1-receptor antagonist and thereby mediates the contraction of smooth muscle and the dilation and increased permeability of the capillaries.

Special precautions for storage
Keep containers well closed. Protect from light. Store below 25°C.

Lagaay International BV
Van Helmontstraat 99
3029 AA Rotterdam, The Netherlands
Tel: +31 - 10 4123871