Prescribing Information/Insert

PIRITON™

Each tablet contains 4mg chlorphenamine maleate.
Each 10ml of syrup contains 4mg chlorphenamine maleate.

EXCIPIENTS

Tablet: Maize Starch, Lactose, Pregelatinised Maize Starch (Amigel), Magnesium Stearate

Syrup: Sodium Citrate, Citric Acid, Glycerol (Glycerin), Menthol, Vanillin, Fruit Flavor Liquid 15.81.0320, Hypromellose Type 2910/ Hydroxy Propyl Methyl Cellulose 2910, Saccharin Sodium, Sodium Benzoate, Purified Water

INDICATIONS

For symptomatic control of all allergic conditions responsive to antihistamines, including: hay fever, vasomotor rhinitis, urticaria, food allergy, drug and serum reactions, insect bites. For symptomatic relief of itch associated with chickenpox.

DOSAGE AND ADMINISTRATION

Oral administration only. Do not exceed the stated dose or frequency of dosing.

Tablet

Adults and children aged 12 years and over: One tablet (4 mg) every 4 to 6 hours. Maximum daily dose: Six tablets (24 mg) in any 24 hours.

Elderly: One tablet (4 mg) every 4 to 6 hours. Maximum daily dose: Three tablets (12 mg) in any 24 hours.

Children 6 to 11 years: Half a tablet (2 mg) every 4 to 6 hours. Maximum daily dose: Six half tablets (12 mg) in any 24 hours.

Children under 6 years: Not recommended for children under the age of 6 years.

Syrup

Adults and children aged 12 years and over: 10 ml (4 mg) every 4 to 6 hours. Maximum daily dose: 60 ml (24 mg) in any 24 hours.

Elderly: 10 ml (4 mg) every 4 to 6 hours. Maximum daily dose: 30 ml (12 mg) in any 24 hours.

Children 6 to 11 years: 5 ml (2 mg) every 4 to 6 hours. Maximum daily dose: 30 ml (12 mg) in any 24 hours.

Children 2 to 5 years: 2.5 ml (1 mg) every 4 to 6 hours. Maximum daily dose: 15 ml (6 mg) in any 24 hours.

Infants 12-23 months: 2.5 ml (1 mg) twice daily. The minimum interval between the doses should be 4 hours. Maximum daily dose: 5 ml (2 mg) in any 24 hours.

Infants under 12 months: Not recommended for infants under the age of 12 months.

Populations

Renal Impairment

Medical advice should be sought for those with severe renal impairment.

Hepatic Impairment

Medical advice should be sought for those with severe hepatic impairment.

CONTRAINDICATIONS

Patients with a history of hypersensitivity to chlorphenamine maleate, antihistamines or to any of the product constituents. Patients who have been treated with monoamine oxidase inhibitors (MAOIs) within the previous fourteen days, as the anticholinergic properties of chlorphenamine are intensified by MAOIs.

WARNINGS AND PRECAUTIONS

Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy, severe hypertension and cardiovascular disease, raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hepatic impairment, severe renal impairment, bronchitis, bronchiectasis and bronchial asthma.

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.

Chlorphenamine may increase the effects of alcohol and therefore concurrent use should be avoided. Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics maycause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Should not be used with other anti-histamine containing products, including antihistamine containing cough and cold preparations. Keep out of sight and reach of children.

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

INTERACTIONS

Concurrent use of chlorphenamine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect. (See Warnings and Precautions). Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity. The anticholinergic effects of chlorphenamine are intensified by MAOIs (see Contraindications).

PREGNANCY AND LACTATION

Pregnancy

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 essential by a physician.

Lactation

Chlorphenamine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

ABILITY TO PERFORM TASKS THAT REQUIRE JUDGEMENT, MOTOR OR COGNITIVE SKILLS

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 (see Warnings and Precautions).

ADVERSE REACTIONS

Frequency unknown: allergic reactions, angioedema, anaphylactic reactions, anorexia, confusion*, excitation*, irritability*, nightmares*, Hypotension, thickening of bronchial secretions, vomiting, abdominal pain, diarrhoea, dyspepsia, exfoliative dermatitis, rash, urticaria, photosensitivity, muscle twitching, muscle weakness, urinary retention, chest tightness,

Very common: sedation, somnolence

Common: disturbance in attention, abnormal coordination, dizziness, headache, blurred vision, nausea, dry mouth, fatigue

*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

OVERDOSAGE

Symptoms and Signs

Overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include paradoxical excitation, toxic psychosis, convulsions, apnoea, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Treatment should be supportive and directed towards specific symptoms. Convulsions and marked CNS stimulation should be treated with parenteral diazepam.

SHELF-LIFE

Tablet: 36 months; Syrup: 24 months

STORAGE

Store below 30^0C, away from light

NATURE AND CONTENT OF CONTAINER

Tablet: 50x10's in polycoated paper foil strips
Syrup: 100 ml in amber glass bottle

MANUFACTURED BY:

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