

Piriton

Chlorpheniramine Maleate



Presentation

Piriton Tablets: Round, biconvex white tablets each containing Chlorpheniramine maleate B.P. 4mg.
Identification: Engraved Piriton round the perimeter of one side.

Piriton Syrup: Each 5ml of Piriton syrup contains Chlorpheniramine maleate B.P. 2mg. It is colourless.

Piriton Expectorant: Each 5ml dose of Piriton Expectorant contains 2mg Chlorpheniramine maleate B.P. 100mg Ammonium chloride B.P. and 44mg Sodium citrate B.P. It is a clear brownish-yellow viscous liquid with an odour of cherries.



Clinical Pharmacology

Chlorpheniramine maleate is a potent antihistamine (H1 receptor antagonist). Antihistamine diminish or abolish the actions of histamine in the body by competitive reversible blockade of H1 receptor sites on tissues. Ammonium chloride is an expectorant, which by a reflex irritant action increases the volume of secretions in the respiratory tract and therefore facilitates their removal by ciliary action and coughing.

Clinical Pharmacokinetics

Chlorpheniramine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occur about 2.5-6 hrs after administration by mouth. Bioavailability is low, about 25-50%. It appears to undergo considerable first-pass metabolism. About 70% of Chlorpheniramine maleate is bound to plasma proteins. Chlorpheniramine maleate is widely distributed in the body, including passage into the CNS. Chlorpheniramine maleate is extensively metabolised. Its 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.

Indications

Piriton tablets and syrup are indicated for symptomatic control of all allergic conditions responsive to antihistamines including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites.
 Piriton Expectorant Linctus is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough, including the common cold and bronchitis.

Excipients

Piriton Tablet: Lactose B.P., Maize Starch B.P., Maize Starch Pregelatinised B.P., Magnesium Stearate B.P., Purified Water B.P.
Piriton Expectorant: Alcohol 96% B.P., Aniseed oil B.P., Cherry Mavella Flavour, Citric Acid anhydrous B.P., Crème de menthe essence, Glycerol B.P., Levomenthol B.P., Liquid Glucose (SO₂ free) B.P., Liquorice Liquid extract B.P., Nipaset, Sodium citrate B.P., Vanilin B.P., White Refined sugar, Purified Water B.P.

Piriton Syrup: Alcohol 96% B.P., Glycerol B.P., Nipaset, Tingle Flavour, Peppermint Oil B.P., White Refined sugar B.P., Purified Water B.P.

Dosage and administration

For the relief of cold symptoms:
 Do not use continuously for more than one week without consulting a doctor.
 For symptomatic control of allergic conditions and relief of itch associated with chickenpox:
 Do not use continuously for more than two weeks without consulting a doctor.
 For all indications:

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

Minimum interval between the doses should be 4 hours.

Piriton Syrup:

Adults and Children aged 12 years and over: Two 5ml spoonfuls every 4 to 6 hours. (daily max: 24mg i.e. 60ml).

Children between 6-11 years: one 5ml spoonful every 4 to 6 hours. (daily max: 12mg i.e. 30ml).

Children between 2 to 5 years (under Medical advice): One dose of 2.5 ml every 4 to 6 hours (daily max: 6 mg i.e. 15ml)

Infants under 2 years: Not recommended.

Elderly: 10ml (4mg) every 4 to 6 hours (daily max 12mg i.e. 30ml)

Piriton Tablets:-

Adults and Children aged 12 years and over: 1 tablet every 4 to 6 hours. Daily dose should not exceed 24mg (6 tablets).

Children 6 to 11 years: Half a tablet (2mg) every 4 to 6 hours (daily max: Six half tablets (12mg).

Children under 6 years: Not recommended.

Elderly: 1 tablet every 4 to 6 hours. Daily dose should not exceed 12mg (3 tablets).

Piriton Expectorant:-

Adults: Two 5ml spoonfuls every 4 to 6 hours (daily max: 24mg i.e. 60ml).

Elderly: 10ml (4mg) every 4 to 6 hours (daily max: 12mg i.e. 30ml).

Children between 6-11 years: one 5ml spoonful every 4 to 6 hours (daily max: 12mg i.e. 30ml).

Children & Elderly: The minimum interval between the doses should be 4 hours.

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

Contra-indications

Patients with a history of hypersensitivity to Chlorpheniramine Maleate or to any of the product constituents.
 Patients that have had monoamine oxidase inhibitor therapy within the previous fourteen days.

Precautions

Check with a doctor before use if you are taking medicines to treat anxiety or to help you sleep.

Caution is required when there is concurrent usage of alcohol as Piriton Syrup and Piriton Expectorant contain 6.0, 6.5% v/v and 3, 4% v/v ethanol (alcohol) respectively. This should be taken into consideration as it is harmful for those suffering from alcoholism. To be taken into account in pregnant



or breast-feeding women, children and patients at higher risk of alcohol associated problems, such as patients with liver disease or epilepsy. Chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patient's ability to drive and operate machinery.

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

Long term treatment with Piriton Syrup/Expectorant increase the risk of dental caries and it is essential that adequate dental hygiene is maintained. As Piriton syrup contains 2.36g of sucrose per 5ml and Piriton Expectorant contains 1.95g of sucrose per 5ml, it should be administered with care to patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Should not be used with other antihistamine containing products including antihistamine containing cough and cold preparations.

Chlorpheniramine may increase the effects of alcohol and therefore consumption use should be avoided.

Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Avoid use of the product in elderly patients with confusion.

Pregnancy and lactation

Piriton should be only used during pregnancy when clearly needed and when the potential benefit to the mother outweighs the potential risk to the foetus.

Use by nursing mothers is not recommended because of the risks of adverse effects in the infants.

Adverse reactions

When using this product you may experience:

Sedation and drowsiness (somnolence) which are very common

Dizziness, headache, blurred vision, nausea, dry mouth, fatigue, disturbance in attention and abnormal co-ordination which may occasionally occur.

Allergic reactions, angioedema, anaphylactic reactions, anorexia, confusion, excitation, irritability, nightmares, hypertension, thickening of bronchial secretions, vomiting, abdominal pain, diarrhoea, dyspepsia, exfoliative dermatitis, rash, urticaria, photosensitivity, muscle twitching, muscle weakness, urinary retention and chest tightness may occur.

Stop using this product and consult your doctor if you experience: Allergic reactions which can be severe. Signs include:

- Raised and itchy rash (hives);
- Swelling, sometimes of the face or mouth causing difficulty in breathing;
- Collapse
- Difficulty in passing water

These reactions are rare.

Children and elderly are more susceptible to adverse events

Overdose

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

If you take more medicine than you should, seek medical advice immediately.

Treatment

Management should be as clinically indicated or as recommended by the national poison centre.

Drug Interactions

Concurrent use of Chlorpheniramine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect.

As monoamine oxidase inhibitor therapy intensifies the anticholinergic effects of Chlorpheniramine concurrent therapy is contra-indicated.

Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

Pharmaceutical precautions

Piriton Tablets: Store below 30°C.

Piriton Syrup: store below 30°C and protect from light.

Piriton Expectorant: store below 30°C and protected from light.

Further information:

No Piriton preparation contains tartrazine.

Keep out of sight and reach of children

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We value your feedback

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GSK is committed to the effective collection and management of human safety information relating to our products and we encourage healthcare professionals to report adverse events to us.

Manufactured by:

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PIRITON LEAFLET-FRONT

PIRITON LEAFLET-BACK

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Product Market Trade Name: piriton	Approving Market(s):	Material Spec: XXX	
Print Process:	Colour Standard Reference: XXX	Material Type: XXX	XXXX
Total Colours & Varnishes: X		Body Text Size: XXX	Smallest Text Size: XXX
		Leading: XXX	
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