SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine Maleate 4 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorphenamine Maleate BP 4 mg

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults:	4 mg every 4-6 hours (daily maximum 24 mg)
Children:	Under 1 year – Not recommended
	1 to 2 years – 1 mg twice daily
	2 to 5 years – 1 mg every 4-6 hours (daily maximum 6 mg)
	6 to 12 years – 2 mg every 4-6 hours (daily maximum 12 mg)
Elderly:	Same as adult dose although these patients may be more prone to confusional psychosis and other neurological anticholinergic effects.

Tablets to be taken by mouth.

4.3 Contraindications

There are no specific contraindications.

4.4 Special warnings and precautions for use

Effects of alcohol may be increased. Use with caution in epilepsy, prostatic hypertrophy, glaucoma, urinary retention, pyloduodenal obstruction, hepatic disease, bronchitis, thyrotoxicosis, raised intra-ocular pressure, severe hypertension or cardiovascular disease and bronchial asthma. Children and the elderly are more likely to experience the neurological anticholinergic effects.

4.5 Interaction with other medicinal products and other forms of interaction

Enhances the action of any sedative, hypnotic or other central depressant drug given concurrently. Alcohol should be avoided during treatment. MAO inhibitor therapy intensifies the anticholinergic effects of chlorphenamine. Chlorphenamine inhibits phenytoin metabolism leading to phenytoin toxicity.

4.6 Pregnancy and lactation

Do not use in pregnancy unless the physician considers it essential.

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.

4.7 Effects on ability to drive and use machines

Patients receiving Chlorphenamine should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the Central Nervous System effects of the drug and do not suffer from confusion, disorientation or dizziness.

4.8 Undesirable effects

Sedation varying from slight drowsiness to deep sleep. Inability to concentrate, lassitude, blurred vision, gastro-intestinal disturbances such as nausea, vomiting, diarrhoea, dyspepsia. Urinary retention, headaches, dryness of the mouth, difficulty in lachrymation and constipation. Dizziness, palpitations, tachycardia, arrhythmias, hypotension, tightness of the chest, abdominal pain, anorexia, hepatitis including jaundice, thickening of bronchial secretions, haemolytic anaemia and other blood dyscrasias. Allergic reactions including bronchospasm, angioedema and anaphylaxis, exfoliative dermatitis, photosensitivity and skin reactions such as urticaria. Extrapyramidal effects, twitching, muscular weakness and incoordination. Tinnitus, confusion, depression, tremor, convulsions, irritability and nightmares. Paradoxical excitation in the children and confusional psychosis in the elderly can occur.

4.9 Overdose

The symptoms in children are characterised by various combinations of excitation, ataxia, inco-ordination, athetosis and hallucinations. Adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children; coma or excitement may precede their occurrence. Cardiorespiratory depression is uncommon.

If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha, this despite the anti-emetic effect of the drug. Alternatively gastric lavage may be used. Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with Diazepam or other suitable anticonvulsant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic 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 H_1-receptor antagonist and thereby mediates the contraction of smooth muscle and the dilation and increased permeability of the capillaries.

5.2 Pharmacokinetic properties

Chlorphenamine maleate is well absorbed after oral dosing with extensive first-pass effect. It is highly bound to plasma proteins. It is slowly excreted via urine and bile. It is distributed widely in the body. It enters the brain and crosses the placenta. Phenothiazines pass into the milk at low concentrations.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, maize starch, povidone K25, quinoline yellow E104, magnesium stearate, sodium starch glycollate.

6.2 Incompatibilities

Chlorphenamine Maleate is incompatible with alkaline substances which precipitate Chlorphenamine Base.

6.3 Shelf life

3 years in polystyrene containers;
24 months in PVC/Aluminium foil blister packs.

6.4 Special precautions for storage

Keep containers well closed, protect from light, store below 25°C.

6.5 Nature and contents of container

Securitainer-type or opaque plastic screw capped containers of 100, 500 or 1000 tablets.

Blister packs of 10 or 30 tablets.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

15/12/2008