SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine 4 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4 mg Chlorphenamine Maleate.
Also contains lactose and sunset yellow (E110). For the full list of excipients see 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Yellow, circular normal convex tablets with a breakline embossed C / 4 on one face and PV on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic control of allergic conditions which respond to anti-histamines including hay fever, urticaria, vasomotor rhinitis, angioneurotic oedema, food allergies, drug and serum reactions, pruritis vulvae, pruritis ani, and insect bites.
Also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

For oral use
Adults and children over 12 years: 4mg (one tablet) every 4 to 6 hours (maximum 24 mg daily).

Children: Aged 6 –12 years: 2mg (equivalent to half a tablet) every 4 to 6 hours
(Maximum 12mg daily)
Not recommended for children under 6 years of age.

Elderly: As for adults but such patients are prone to confusional psychosis and other neurological anticholinergic effects.
Consideration should be given to using a lower daily dose (e.g. a maximum of 3 tablets (12mg in total) in any 24 hours, taken 1 tablet 4 to 6 hourly.

4.3 Contraindications

1. Use in patients hypersensitive to Chlorphenamine or any of the excipients in the tablet.
2. Coma or pre-coma states.
3. Known brain damage or epilepsy.

   The anticholinergic properties of Chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine is therefore contraindicated in patients who have been treated with MAOIs within the last fourteen days.

4.4 Special warnings and precautions for use

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, 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 disease and thyrotoxicosis.

Sedation inappropriate in severe liver disease, avoid use of chlorphenamine.

Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

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

This medicine contains sunset yellow (E110), which can cause allergic- type reaction including asthma. Allergy is more common in those people who are allergic to aspirin.

This medicine also contains lactose. Patient with rare hereditary problems of glactose intolerance, the Lapp lactase deficiency of glucose-glactose malabsorption should not take this medicine.

Keep all medicines out of sight and reach of children

4.5 Interaction with other medicinal products and other forms of interaction

Chlorphenamine may potentiate the sedative effects of alcohol and other CNS depressants. The effects of anticholinergic drugs may also be potentiated.

Chlorphenamine may antagonise the effects of betahistine.

Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, 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 (see Contraindications)

Lopinavir may increase the plasma concentration of chlorphenamine.

4.6 Fertility, pregnancy and lactation

Chlorphenamine should not be used in pregnancy and lactation except when considered essential by the physician. 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.

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

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'. Therefore the patients are advised not to drive or operate machinery whilst taking Chlorphenamine tablets.

4.8 Undesirable effects

Cardiac disorders: rarely palpitation, tachycardia, arrhythmias.

Blood and lymphatic system disorders: rarely haemolytic anaemia and other blood dyscrasias.

Immune system disorders: Unknown allergic reaction, angioedema, anaphylactic reactions

Nervous system disorders:* Most commonly sedation, somnolence

Commonly, dizziness, headache, impaired concentration ability, abnormal coordination and psychomotor impairment.

Occasionally insomnia, nervousness, tremors, convulsions.

Eye disorders: commonly blurred vision.

Ear and labyrinth disorders: rarely tinnitus.

Respiratory, thoracic and mediastinal disorders: rarely increased viscosity of bronchial secretions

Gastrointestinal disorders: Commonly gastro-intestinal disturbances such as nausea, vomiting, diarrhoea. Occasionally 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 rash, urticaria.

Musculoskeletal and connective tissue disorders: rarely twitching and muscular weakness.

Vascular disorders: rarely hypotension.

General disorders and administration site conditions: commonly fatigue. Occasionally lassitude; rarely dizziness, tightness of chest and irritability.

Hepatobiliary disorders: rarely hepatitis, including jaundice.

Psychiatric disorders: rarely depression, nightmares*, confusion*, excitation*, irritability*.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms and signs

The estimated lethal dose of Chlorphenamine is 25 to 50 mg/kg body weight. Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, 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.

Treatment of overdose should include gastric lavage or induced emesis using Syrup of Ipecacuanha. Following these measures activated charcoal and cathartics may be administered to minimise absorption.

Hypotension and arrhythmias should be treated vigorously; CNS convulsions may be treated with 'i.v.' diazepam or phenytoin. Haemoperfusion may be used in severe cases.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code R06AB04 Antihistamines for systemic use

Chlorphenamine is a potent antihistamine (H1-antagonist).
Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-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.

5.2 Pharmacokinetic properties

Chlorphenamine is well absorbed from the gastro-intestinal tract and following oral administration the effects develop within 30 minutes, are maximal within 1 to 2 hours and last about 4 to 6 hours. The drug is widely distributed throughout the body including the CNS. Little if any is excreted unchanged in the urine; most appears there as degradation products that are almost completely excreted within 24 hours. The main site of metabolic transformation is the liver. The drug is eliminated more rapidly by children than by adults.

5.3 Preclinical safety data

There are no Preclinical 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 monohydrate, maize starch, quinoline yellow (E104), sunset yellow (E110), magnesium stearate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Do not store above 25ºC

Keep the polypropylene securitainer tightly closed.

Store in the original polypropylene securitainer.

6.5 Nature and contents of container

Polypropylene securitainer with lids.

Pack sizes: 30, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Pharmvit Limited
Derby Road
Greenford
Middlesex
UB6 8UJ

8 MARKETING AUTHORISATION NUMBER(S)

PL 04556/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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