1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

Chlorphenamine Maleate Tablet 4 mg

2. Composition:

Each un coated tablet contains

Chlorphenamine Maleate	USP	4 mg
Excipients		q.s.

3. Pharmaceutical Form:

Solid Oral Uncoated Tablet

4. Clinical Particulars

Therapeutic indications

Chlorphenamine Maleate 4 mg tablets 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.

Also indicated for the symptomatic relief of itch associated with chickenpox.

Posology and method of administration

Oral Administration only

Do not exceed the stated dose or frequency of dosing

Adults and children 12 years and over: 1 tablet 4 to 6 hourly. Maximum daily dose: 6 tablets (24 mg) in any 24 hours

Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g. a maximum of 12 mg in any 24 hours).

Children aged 6 - 12 years: ½ tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) in any 24 hours

Not recommended for children under 6 years

Contraindications

Chlorphenamine Maleate 4 mg tablets are contra-indicated in patients who are hypersensitive to antihistamines or to any of the tablet ingredients.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine Maleate 4 mg Tablets is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.

Special warnings and precautions for use

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 or asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to

experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

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.

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.

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

Keep out of sight and reach of children.

Interaction with other medicinal products and other forms of interaction

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 Contra-indications).

Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of chlorphenamine maleate in pregnant women. The potentisl 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 essentially by a physician.

Lactation

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

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.

Undesirable effects

Specific estimation of the frequency of adverse events for OTC products is inherently difficult (particularly numerator data). Adverse reactions which have been observed in clinical trails and which are considered to be common (occurring in ≥1% to <10% of subjects) or very common (occurring in ≥10% of subjects) are listed below by MedDRA Sytem Organ Class. The frequency of other adverse reactions identified during post-marketing use is unknown.

Blood and lymphatic system disorders:

Unknown: haemolytic anaemia, blood dyscrasias

Immune system disorders:

Unknown: allergic reaction, angioedema, anaphylactic reactions

Metabolism and nutritional disorders:

Unknown: anorexia

Psychiatric disorders:

Unknown: confusion*, excitation*, irritability*, nightmares*, depression

Nervous system disorders*:

Very common: sedation, somnolence

Common: disturbance in attention, abnormal coordination, dizziness headache

Eye Disorders:

Common: blurred vision

Ear and labyrinth disorders:

Unknown: tinnitus

Cardiac disorders:

Unknown: palpitations, tachycardia, arrythmias

Vascular disorders:

Unnown: Hypotension

Respiratory, thoracic and mediastinal disorders:

Unknown: thickening of bronchial secretions

Gastrointestinal disorders:

Common: nausea, dry mouth

Unknown: vomiting, abdominal pain, diarrhoea, dyspepsia

Hepatobiliary disorders:

Unknown: hepatitis, including jaundice

Skin and subcutaneous disorders:

Unknown: exfoliative dermatitis, rash, urticaria, photosensitivity

Musculoskeletal and connective tissue disorders:

Unknown: muscle twitching, muscle weakness

Renal and urinary disorders:

Unknown: urinary retention

General disorders and administration site conditions:

Common: fatigue

Unknown: chest tightness

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

Overdose

Symptoms and signs

The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, 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. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5. Pharmacological properties

Pharmacodynamic properties

ATC Code R06AB02

Chlorphenamine is a potent antihistamine (H_1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H_1-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.

Pharmacokinetic properties

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

List of excipients

Tablet core

Lactose

Maize Starch

Yellow Iron Oxide (E172)

Magnesium Stearate

Purified Water

Incompatibilities

None reported.

Shelf life

3 years

Special precautions for storage

Do not store above 30°C

Nature and contents of container

10x10 strip pack

Special precautions for disposal and other handling

No special requirements.

7. Marketing Holder

ZADIP HEALTHCARE LTD

ONITSHA, ANAMBRA STATE, NIGERIA

8. Manufacturer

COMED CHEMICALS LTD, INDIA