1 NAME OF THE MEDICINAL PRODUCT

Hayleve

Chlorphenamine Maleate 4 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains chlorphenamine maleate 4 mg.

Excipient(s) with known effect: Lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Biconvex pale yellow scored (*).

(*) Score is in the form of a cross break-line.

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The tablets are indicated for symptomatic control of all allergic conditions responsive to antihistamines, including urticaria, hayfever, food allergy, drug and serum reactions, insect bites, vasomotor rhinitis and angioneurotic oedema.

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

4.2 Posology and method of administration

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Do not exceed the stated dose or frequency of dosing.

Minimum doing interval : 4 hours

Do not use continuouly for more than two weeks without consulting a doctor.

Adults and children over 12 years: 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: 1/2 tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12 mg) in any 24 hours.

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

Populations

Patients with renal or hepatic impairment should seek doctor's advice prior to taking this medicine. (See Section 4.4 Special warnings and precautions for use).

Method of aministration

Oral Administration only

4.3 Contraindications

The tablets are contra-indicated in patients who are hypersensitive to the active substsnce, other antihistamines or to any of the excipient listed in section 6.1.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitor (MAOIs). The tablets are therefore contra-indicted in patients who have been treated with MAOIs within the last 14 days.

4.4 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; hepatic impairment, renal impairment, bronchitis, bronchiectasis or asthma severe hypertension or cardiovascular disease. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg.Increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

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.

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

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

This medicine contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Keep out of sight and reach of children.

4.5 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, concurrent use of alcohol may have a similar effect; 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).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of chlorphenamine maleate in pregnant women. The potential risk for human 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.

Breast-feeding

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.

4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may causes drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patient's ability to drive and use machinery.

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1000 to 1/100), rare (>1/10,000 to <1/1000) and very rare (<1/10,000), not know (cannot be estimated from available data).Adverse reactions identified during post-marketing use with chlorphenamine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

System Organ Class	**Adverse Reaction**	**Frequency**
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness headache	Common
Eye disorders	Blurred Vision	Common
Gastrointestinal disorders	Nausea, dry mouth	Common
	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
Immune system disorders	Allergic reaction, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown

Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrythmias	Unknown
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown

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

Reporting of suspected adverse reactions

Reporting suspected adverse reaction 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms and signs

The estimated lethal dose of chlorphenamine is 25 to 50 mg/kg bodyweight. Symptoms and signs include sedation, paradoxic stimulation of the CNS, toxic psychosis, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available.

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.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Substituted alkylamines, ATC code R06AB04

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.

5.2 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 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. Only traces amounts have been found in the faeces.

5.3 Preclinical safety data

No additional data of relevance.

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 is incompatible with alkaline substances which precipitate Chlorphenamine Base.

6.3 Shelf life

Plastic containers:	36 months
Blister-packs:	48 months

6.4 Special precautions for storage

Keep containers well closed. Protect from light. Store below 25°C.

6.5 Nature and contents of container

High density polystyrene with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane or polythene inserts.
Pack sizes: 100, 500 and 1,000.

PVC/Aluminium foil blister packs.
Pack sizes: 10, 28, 30 and 60.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Hualan Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 52104/0017

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19 July 2000

10 DATE OF REVISION OF THE TEXT

24/06/2023