SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine Maleate 2 mg/5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 2 mg of chlorphenamine maleate.

Excipients with known effect:

Sodium methyl parahydroxybenzoate (E219) 9 mg/5 ml

Sodium propyl parahydroxybenzoate (E217) 1 mg/5 ml

Maltitol Liquid (E965) 1.0 ml/5 ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorphenamine Oral Solution is indicated for the symptomatic control of all allergic conditions responsive to antihistamines including hay fever, allergic rhinitis, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites. It is also indicated for the symptomatic relief of itch associated with chickenpox.

4.2 Posology and method of administration

Posology

Do not exceed the stated dose or frequency of dosing.

Age	Dose
Children below 1 year:	Not recommended.
Children aged 1 - 2 years:	2.5ml (1mg) twice daily. The minimum interval between the doses should be 4 hours. Maximum daily dose: 5ml (2mg) in any 24 hours.
Children aged 2 - 6 years:	2.5ml (1mg) every 4 to 6 hours. Maximum daily dose: 15ml (6mg) in any 24 hours.
Children aged 6 - 12 years:	5ml (2mg) every 4 to 6 hours. Maximum daily dose: 30ml (12mg) in any 24 hours.
Adults and children 12 years and over:	10ml (4mg) every 4 to 6 hours. Maximum daily dose: 60ml (24mg) in any 24 hours.

Not recommended for children below 1 year.

Special populations

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 12mg in any 24 hours).

Method of administration
For oral use.

4.3 Contraindications

Hypersensitive to the active substance or to any of the excipients listed in section 6.1.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine Oral Solution is therefore contraindicated in patients who have been treated with MAOIs within the last fourteen days (see section 4.5).

4.4 Special warnings and precautions for use

Chlorphenamine in common with other medicinal products 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, pyloroduodenal obstruction and thyrotoxicosis.

Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (*e.g.* 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.

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

Chlorphenamine Oral Solution contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217). These may cause allergic reactions (possibly delayed).

It also contains maltitol liquid (E965). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

This medicine may enhance the sedative effects of alcohol, hypnotics, anxiolytics, sedatives, opioid analgesics and neuroleptics, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

The antimuscarinic effects of chlorphenamine are enhanced by other antimuscarinic medicinal products and both anticholinergic and sedative effects are enhanced by monoamine oxidase inhibitors (MAOIs) (concurrent therapy with which is contraindicated, see 4.3 above) and tricyclic antidepressants.

Metabolism of phenytoin may be inhibited by Chlorphenamine with the possible development of phenytoin toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of chlorphenamine in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the new born or premature neonates. Not to be used during pregnancy unless considered essential by a physician.

Breast-feeding

Chlorphenamine maleate and other antihistamines may inhibit lactation and may be secreted in human milk and its use is not recommended in breast-feeding mothers because of the risk of adverse events such as unusual excitement or irritability in infants. 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 cause drowsiness; dizziness, blurred vision and psychomotor impairment which can seriously hamper patient's ability to drive and use machinery.

4.8 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 trials and which are considered to be Common (≥1/100 to <1/10) or Very common (≥1/10) are listed below by MedDRA System Organ Class. The frequency of other adverse events identified during post-marketing use that cannot be estimated from the available data is Not known.

System Organ Class	Frequency of occurrence		
	Very common	**Common**	**Not known**
Blood and lymphatic system disorders			haemolytic anaemia, blood dyscrasias
Immune system disorders			allergic reaction, angioedema, anaphylactic reactions
Metabolism and nutritional disorders			anorexia
Psychiatric disorders			confusion*, excitation*, irritability*, nightmares*, depression
Nervous system disorders*	sedation, somnolence	disturbance in attention, abnormal coordination, dizziness, headache	
Eye disorders		blurred vision	
Ear and labyrinth disorders			tinnitus
Cardiac disorders			palpitations, tachycardia, arrhythmias
Vascular disorders			hypotension
Respiratory, thoracic and mediastinal disorders			thickening of bronchial secretions
Gastrointestinal disorders		nausea, dry mouth	vomiting, abdominal pain, diarrhoea, dyspepsia
Hepatobiliary disorders			hepatitis including jaundice

Skin and subcutaneous disorders			exfoliative dermatitis, rash, urticaria, photosensitivity
Musculoskeletal and connective tissue disorders			muscular twitching, muscle weakness
Renal and Urinary disorders			urinary retention
General disorders and administration site conditions		fatigue	chest tightness

*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (*e.g.* 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 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 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the Central Nervous System (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 overdose 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 intravenous diazepam. Haemoperfusion may be used in severe cases.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, 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 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.

5.3 Preclinical safety data

No additional data of relevance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Maltitol Liquid (E965)

Citric Acid Monohydrate

Sodium Methyl parahydroxybenzoate (E219)

Sodium Propyl parahydroxybenzoate (E217)

Strawberry Flavour (contains Propylene Glycol)

Saccharin Sodium

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC.

Store in the original container.

6.5 Nature and contents of container

Amber Type III glass bottle.

Child resistant, tamper-evident polypropylene cap.

2.5 / 5ml-measuring spoon is supplied

Pack sizes: 100ml and 150ml bottle.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0610

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/08/2021

10 DATE OF REVISION OF THE TEXT

20/08/2021