

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Allerief 2mg/5ml Oral Solution
Chlorphenamine Maleate 2mg/5ml Oral Solution
Lloyds Pharmacy Allergy Relief Antihistamine 2mg/5ml Oral Solution
Numark Antihistamine and Allergy Relief 2mg/5ml Oral Solution
Careway Allergy Relief Antihistamine 2mg/5ml Oral Solution
Almus Chlorphenamine Maleate 2mg/5ml Oral Solution
Well Pharmaceuticals Allergy Syrup Relief 2mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains 2mg of Chlorphenamine Maleate.

Excipients with known effect:

Sodium methyl parahydroxybenzoate (E219) 9mg/5ml
Sodium propyl parahydroxybenzoate (E217) 1mg/5ml
Maltitol Liquid (E965) 1.0ml/5ml (1.37g/5ml)
Propylene glycol (E1520) 5mg/5ml

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

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.

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

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

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).

Populations

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

Method of administration

For oral administration.

4.3 Contraindications

Contra-indicated in patients who are hypersensitive to the active substance, other antihistamines or to any of the excipients listed in section 6.1.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine is therefore contra-indicated 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 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 impairment, renal impairment.

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

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

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.

Excipients:

This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217). These may cause allergic reactions (possibly delayed).

This medicine contains Maltitol Liquid (E965). Patients with rare hereditary problems of fructose intolerance should not take this medicine. Maltitol may have mild laxative effect. Each 5ml dose provides 1.37g maltitol (3.1 kcal).

This medicine contains 5mg of propylene glycol (E1520) per 5ml which is equivalent to 1mg/ml.

This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially sodium free.

Keep out of the 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.

The anticholinergic effects of chlorphenamine are intensified by MAOIs (see section 4.3).

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no adequate 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 breast milk and its use is not recommended in nursing 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

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 known (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	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 CNS, toxic psychosis, convulsions, apnoea, 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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, substituted alkylamines, ATC code: R06AB04

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, 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 (E422)

Maltitol Liquid (E965)

Citric Acid Monohydrate

Sodium Methyl parahydroxybenzoate (E219)

Sodium Propyl parahydroxybenzoate (E217)

Strawberry Flavour (contains Propylene Glycol E1520, Flavouring Substances and Ascorbic Acid)

Saccharin Sodium

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Do not store above 25°C. 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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Key House
Sarum Hill
Basingstoke
RG21 8SR
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0519

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/12/2008

10 DATE OF REVISION OF THE TEXT

03/10/2024