SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Children's Allergy Relief Antihistamine 2mg/5ml Syrup
Chlorphenamine Maleate 2mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	mg/5ml
Chlorpheniramine maleate (INN Name: Chlorphenamine maleate)	2.0
Excipient(s) with known effect	
Maltitol liquid	0.75ml/5ml
Sodium benzoate	10mg/5ml
Ethyl alcohol	1.6mg/5ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of hayfever, vasomotor rhinitis, urticaria, angioneurotic oedema, reactions to food or medicines, serum reactions and insect bites.

4.2 Posology and method of administration

Adults and children over 12 years
Two 5ml doses every four to six hours up to a maximum of six doses in 24 hours as required.

Children 6 to 12 years
One 5ml dose every four to six hours up to a maximum of six doses in 24 hours as required.

Children 2 to 6 years
One 2.5ml dose every four to six hours up to a maximum of six doses in 24 hours as required.

Children 1 to 2 years
One 2.5ml dose twice a day up to a maximum of two doses in 24 hours as required.

Children under 1 year
Not recommended.

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).

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).

For oral administration.
Do not exceed the stated the stated dose or frequency of dosing.
The minimum interval between the doses should be 4 hours.

4.3 Contraindications

Acute asthma, hypersensitivity to any of the ingredients or other antihistamines. Premature infants or neonates because of their increased susceptibility to the antimuscarinic effects. This medicine should not be given to patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

4.4 Special warnings and precautions for use

This medicine should be given with caution to patients with epilepsy, severe cardiovascular disorders, liver disorders, renal impairment, glaucoma, urinary retention, prostatic enlargement, pyloroduodenal obstruction, asthma, bronchitis, bronchiectasis, thyrotoxicosis and severe hypertension.

Special care should be taken when using chlorpheniramine maleate in children and the elderly as they 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.

If symptoms do not go away within 5 days talk to your pharmacist or doctor.

Keep all medicines out of the reach and sight of children.

Although most antihistamines should be avoided by patients with porphyria, chlorpheniramine maleate has been used and is thought to be safe.

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.

Information about some of the ingredients in this medicine
This medicine contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this. May have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.

This medicine contains 10mg of sodium benzoate in each 5ml dose, which is equivalent to 2mg/ml.

This medicine contains 1.6mg of alcohol (ethanol) in each 5ml dose. The amount in 5ml of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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

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.

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 antimuscarinic effects of chlorpheniramine are enhanced by other antimuscarinic drugs and both antimuscarinic and sedative effects are enhanced by monoamine oxidase inhibitors (concurrent therapy with which is contraindicated, see 4.3 above) and tricyclic antidepressants.

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

4.6 Pregnancy and lactation

There are no adequate controlled studies of chlorpheniramine in pregnant women and this medicine should therefore not be used during pregnancy.

Chlorpheniramine may be secreted in breast milk and its use is not recommended in nursing mothers because of the risk of adverse effects, such as unusual excitement or irritability in infants. Chlorpheniramine may also inhibit lactation.

4.7 Effects on ability to drive and use machines

Chlorpheniramine may cause blurred vision, dizziness, drowsiness and interfere with human performance and therefore may seriously influence the ability to drive and operate 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	**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 tissue 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 susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness)

Glycerol may cause headache, stomach upset and diarrhoea.

Sodium benzoate is a mild irritant to the skin, eyes and mucous membranes. It may increase the risk of jaundice in newborn babies.

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.

5.1 Pharmacodynamic properties

Chlorpheniramine antagonises competitively the effects of histamine on H_1-receptors and also has weak antimuscarinic and moderate antiserotonin and local anaesthetic actions. It penetrates the brain and causes stimulation or sedation in animals.

5.2 Pharmacokinetic properties

Chlorpheniramine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours. The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10L/KG. About 70% of chlorpheniramine in the circulation is protein-bound. Chlorpheniramine undergoes some first pass metabolism and enterohepatic recycling. Chlorpheniramine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the faeces. The mean elimination half life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours.

5.3 Preclinical safety data

The antihistaminic potency of chlorpheniramine is confined mainly to its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)-isomer. The toxicity may therefore be non-specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic H_1antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer.

The experimental data on the carcinogenicity and mutagenicity of chlorpheniramine indicate lack of these adverse effects, but the racemate and the (+)-isomer have shown some embryotoxicity in fertility tests.

Effective antihistaminic concentrations of chlorpheniramine in vitro are about 1-10µg/L and oral doses of 0.2-1 mg/kg antagonise histamine-induced bronchospasm in guinea pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol liquid
Glycerol
Citric acid monohydrate
Sodium benzoate
Flavour natural mint 513484E (including ethyl alcohol)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

36 months.

6.4 Special Precautions for Storage

None.

6.5 Nature and contents of container

150ml, 200ml, 250ml and 300ml amber PET bottle with a child resistant polypropylene cap fitted with an expanded polyethylene liner and, when supplied with a syringe, a polyethylene plug.

Syringe composed of a natural polypropylene barrel and polyethylene pigmented white plunger (optional).

6.6 Instructions for Use, Handling and Disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

Trading as: BCM

8 MARKETING AUTHORISATION NUMBER

PL 00014/0606

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10 December 2003

10 DATE OF REVISION OF THE TEXT

20/06/2023