1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine Elixir 2 mg/5 ml
Lloydspharmacy Allergy Relief Syrup
Almus Allergy Relief 2 mg/5 ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Chlorphenamine Maleate BP 2.0 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sugar free syrup in bottles of 150ml

Colourless syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms caused by allergic conditions such as hayfever, allergic rhinitis, perennial rhinitis, vasomotor rhinitis, urticaria and skin rashes, angioneurotic oedema, drug and serum reactions, food allergy, insect bites etc, which are responsive to antihistamines. 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 the frequency of dosing.
The minimum interval between doses should be 4 hours.
Do not use continuously for more than two weeks without consulting a doctor.

Adults and children 12 years and over: 10 ml (4 mg) every 4 - 6 hourly.
Maximum daily dose: 60 ml (24 mg) in any 24 hours.

Elderly: The elderly are more likely to experience neurological anticholinergic effects. A lower daily dose is recommended (e.g. a maximum of 12 mg in any 24 hours).

Children aged 6 - 12 years: 5 ml (2 mg) every 4 - 6 hourly. Maximum daily dose: 30 ml (12 mg) in 24 hours.
Children aged 2 - 6 years: 2.5 ml (1 mg) every 4 - 6 hourly. Maximum daily dose: 15 ml (6 mg) in 24 hours.

Children aged 1 - 2 years: 2.5 ml (1 mg) twice daily. The minimum interval between the doses should be 4 hours. Maximum daily dose: 5 ml (2 mg) in any 24 hours.

Not recommended for children below 1 year

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 administration
For oral administration.

4.3 Contraindications

Chlorphenamine is contraindicated in patients who are hypersensitive to antihistamines or any of the excipients in the syrup listed in section 6.1.
Chlorphenamine is contraindicated in patients who have had treatment with monoamine Oxidase Inhibitors (MAOI's) within the last 14 days as the anticholinergic properties of chlorphenamine are intensified by MAOI's.

4.4 Special warnings and precautions for use

Chlorphenamine has an anticholinergic effects and should be used with caution in patients with epilepsy, raised intra-ocular pressure including glaucoma, prostatic hypertrophy, severe hypertension, cardiovascular disease, bronchitis, bronchiectasis, asthma, hepatic impairment and renal impairment. Children and the elderly patients 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 should be avoided.
Chlorphenamine should not be used with other antihistamine containing products such as 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.

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

Alcoholic drinks and certain other central nervous system depressants such as anxiolytics or hypnotics can potentiate the sedative effects of chlorphenamine. Therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Phenytoin metabolism is inhibited by chlorphenamine and this can cause phenytoin toxicity.

The anticholinergic effects of chlorphenamine are intensified by the use of other anticholinergic drugs such as atropine, tricyclic antidepressants and MAOI's (see contraindications).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data for the use of chlorphenamine in pregnant women, the potential risk in humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates, therefore it should not to be used during pregnancy unless considered essential by a physician.

Lactation

Chlorphenamine maleate and other antihistamines may inhibit lactation and may be secreted into the breast milk. Should not be used during lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

As with all antihistamines, dizziness, drowsiness, blurred vision and psychomotor impairment may occur. Extreme caution should be advised when driving or operating 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:

Blood and lymphatic system disorders:
Unknown: haemolytic anaemia, blood dyscrasias

Immune system disorders:
Unknown: allergic reaction, angioedema, anaphylactic reactions

Metabolism and nutrition 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, arrhythmias

Vascular disorders:
Unknown: 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 tissue disorders:
Unknown: exfoliative dermatitis, rash, urticaria, photosensitivity

Musculoskeletal and connective tissue disorders:
Unknown: muscular 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 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 (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 - 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 and arrhythmias.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available. Symptomatic and supportive measures giving special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdose occurs by the oral route treat with activated charcoal should be considered, provided there are no contraindications for use and the overdose has been taken recently (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

ATC Code R06AB02

Chlorphenamine is a potent H_1 – blocking drug. Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of the histamine H_1-receptor sites in tissues. Chlorphenamine also has an anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include the inhibition of histamine on smooth muscle, capillary permeability and therefore 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 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

None provided

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol Solution USP
Citric Acid Monohydrate Ph. Eur
Sodium Citrate Ph. Eur
Sodium Benzoate Ph. Eur
Carmellose Sodium Ph. Eur
Strawberry Flavour C9987
Purified Water Ph. Eur

6.2 Incompatibilities

None Stated

6.3 Shelf life

The shelf-life of this product is 36 months

6.4 Special precautions for storage

Store below 25ºC
Protect from light

6.5 Nature and contents of container

Amber glass or PET bottles with HDPE, EPE wadded, tamper evident child resistant closure.

Pack size: 150ml

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ennogen IP Ltd
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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 55612/0067

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/03/2000 / 12/06/2001

10 DATE OF REVISION OF THE TEXT

04/06/2024