SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Chlorpheniramine 2 mg/5 mL oral solution
Chlormine

2. Qualitative and quantitative composition

Each mL of solution contains 0.4 mg of chlorpheniramine.
Each mL of solution contains 2 mg sodium benzoate.

Excipients with known effect
Each mL also contains 0.6 mL of sucrose, 0.2 mL of glucose, 1.8 mg of aspartame and 30 mg of propylene glycol (see section 4.4).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral solution.

Clear, reddish pink solution.

4. Clinical particulars

4.1 Therapeutic indications

Chlorpheniramine is indicated for the symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, and insect bites. Chlorpheniramine 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.

Adults and Children 12 years and over
10ml (4mg) every 4 to 6 hours. Maximum daily dose: 60ml (24mg) 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
5ml (2mg) every 4 to 6 hours. Maximum daily dose: 30ml (12mg) 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 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.

Not recommended for children below 1 year.

Method of administration
Oral administration only.

4.3 Contraindications
Hypersensitivity to chlorpheniramine maleate, any other antihistamines or any of the excipients listed in section 6.1.

The anticholinergic properties of chlorpheniramine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorpheniramine is therefore contraindicated in patients who have been treated with MAOIs within the last fourteen days.

4.4 Special warnings and precautions for use
Chlorpheniramine, 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 or asthma; hepatic impairment; renal impairment.

Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g., increased energy, restlessness, nervousness).

The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect the ability to drive and use machinery.

The effects of alcohol may be increased and therefore concurrent use should be avoided. Should not be used with other antihistamine-containing products, including antihistamine-containing cough and cold medicines.

Excipients
This medicine contains **glucose** and **sucrose**. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains **aspartame**. Aspartame is a source of phenylalanine which may be harmful for patients with phenylketonuria (PKU).

This medicine also contains **propylene glycol**. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old. Administration of propylene glycol to pregnant or lactating patients should be considered on a case-by-case basis. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

4.5 Interaction with other medicinal products and other forms of interaction

Anxiolytics and Hypnotics
concurrent use of chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorpheniramine concurrently with these medicines.

Antiepileptics
Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

Antidepressants
The anticholinergic effects of chlorpheniramine are intensified by MAOIs (see section 4.3 contraindications).

4.6 Pregnancy and lactation

Pregnancy
There is no adequate data on the use of chlorpheniramine in pregnant women. The potential risk for humans 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.

Breastfeeding
Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

No fertility data is available.

4.7 Effects on the ability to drive and use machines
Chlorpheniramine may have a moderate influence on the ability to drive and use machines. The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patient's ability to drive or 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 (occurring in ≥1% to <10% of subjects) or very common (occurring in ≥10% of subjects) are listed below by MedDRA System Organ Class. The frequency of other adverse events identified during post-marketing use is unknown.

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

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

Metabolism and nutritional 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

e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on Google Play or Apple App Store.

4.9 Overdose

Symptoms
The estimated lethal dose of chlorpheniramine 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
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

Pharmacological classification: 5. Antihistamines.

Chlorpheniramine 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. Chlorpheniramine 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 chlorpheniramine 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
Chlorpheniramine 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.
Chlorpheniramine 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 data is available.

6. Pharmaceutical particulars

6.1 List of excipients
Sucrose
Liquid glucose
Sodium benzoate
Anhydrous citric acid
Sodium citrate
Aspartame
Propylene glycol
Essence sweet cherry
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30˚C.

6.5 Nature and contents of the container
A USP type 1 amber glass bottle with a 25 mm “LPL logo” and a printed polypropylene cap with a 10 ml plastic measuring cup.

Fill volume: 100 ml.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
Lincoln Pharmaceuticals Limited
Lincoln House, Science City Road, Sola
Ahmedabad - 380 060
Gujarat
India

8. MANUFACTURER
Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol
Dist. Gandhinagar
Gujarat
India

9. REGISTRATION DETAILS
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