SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal Product

Chlorphenamine Tablets BP

2. Qualitative and Quantitative Composition

Qualitative declaration

Chlorphenamine maleate BP 4 mg

3. Pharmaceutical Form

Solid Oral Dosage Form, Tablets

White to off-white coloured, round shape, biconvex uncoated tablets, plain on both sides.

4. Clinical Particulars

Therapeutic Indications

To relieve the symptoms of allergic conditions such as hay fever (seasonal allergic rhinitis), urticaria, pruritis, food allergy, drug and serum reactions, insect bite or sting reactions, allergies to foods or medicines and angioneurotic oedema.

Posology and Method of Administration

Do not exceed the stated dose or frequency of dosing.

Adults and children over 12 years: 1 tablet 4 to 6 hourly. Maximum daily dose: 6 tablets (24mg in total) 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 3 tablets (12mg in total) in any 24 hours, taken 1 tablet 4 to 6 hourly
Children aged 6-12 years: ½ tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (l2 mg in total) in any 24 hours.
Not recommended for children under the age of 6 years.

Contraindications

Hypersensitivity to chlorphenamine or to any of the excipients. Hypersensitivity to antihistamines.
Patients in coma or patients with brain damage.
Patients on monoamine oxidase inhibitor therapy within the previous 14 day.

Special Warnings and Special Precautions for Use

Use with caution in epilepsy, raised intra-ocular pressure including glaucoma, prostatic hypertrophy; severe hypertension or cardiovascular disease, thyrotoxicosis, urinary retention, bronchitis, bronchiectasis or asthma, hepatic impairment.
Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness)
The effects of alcohol may be increased and therefore concurrent use should be avoided
Should not be used with other antihistamine containing products, including antihistaminecontaining cough and cold medicines.
Special Risk Patients: Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine,
Keep out of sight and reach of children.

Pregnancy: Category B: Safety for use during pregnancy has not been established.

Lactation: May inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

Interaction with other medicinal products and other forms of interaction
Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.Alcohol potentiates sedation due to chlorphenamine.
The risk of antimuscarinic side effects is increased when antihistamines are given with antimuscarinics.
Antidepressants increase the sedative and antimuscarinic effects of anti-histamines. Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase insedative effects.
The anticholinergic effects of chlorphenamine are intensified by MAOIs
Lopinavir may increase the plasma concentration of chlorphenamine.

Pregnancy and Lactation

Pregnancy: Category B: Safety for use during pregnancy has not been established. **Lactation**: May inhibit lactation and may be secreted in breast milk. Not to be used duringlactation unless considered essential by a physician

Effects on ability To Drive and use Machines

Not Applicable

Undesirable Effects

Adverse reactions which have been observed in clinical trials and which are considered tobe common (occurring in > 1% to < 10% of subjects) or very common (occurring in 10 % ofsubjects) are listed below:
Cardiac disorders: Unknown: palpitation, tachycardia, arrhythmias.

Blood and lymphatic system disorders: Unknown: haemolytic anaemia and other

blooddyscrasias
Nervous system disorders: Very common: sedation varying from slight drowsiness to deep sleep, somnolence;
Common: dizziness, headaches and concentration ability impaired, incoordinationEye disorders: Common: blurred vision
Ear and labyrinth disorders: Unknown: tinnitus

Respiratory, thoracic and mediastinal disorders: Unknown: increased viscosity (thickening) of bronchial secretions
Gastrointestinal disorders: Common: nausea, dry mouth; Uncommon: vomiting, diarrhoea, abdominal pain, dyspepsia and anorexia;
Renal and urinary disorders: Unknown: urinary retention

Skin and subcutaneous tissue disorders: Unknown: exfoliative dermatitis, photosensitivity and skin reactions such as urticaria
Musculoskeletal and connective tissue disorders: Unknown: twitching and muscular weakness.
Vascular disorders: Unknown; hypotension

General disorders and administration site conditions: Common: lassitude; uncommon: dizziness, tightness of chest and irritability
Hepatobiliary disorders: Unknown: hepatitis, including jaundice

Psychiatric disorders: Unknown: depression and nightmares. Paradoxical excitation in children and confusional psychosis in the elderly can occur.

Overdose

Estimated lethal dose of Chlorphenamine is 25-50 mg/kg bodyweight.

Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.
Treatment includes gastric lavage or emesis using syrup of ipecac. Following these measures activated charcoal and cathartics may be administered to minimize absorption. Other symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance.
Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with IV diazepam or phenytoin. Hemoperfusion may be used in severe cases.

5. Pharmacological Properties

Pharmacodynamics Properties

Chlorphenamine Maleate is a potent antihistamine (H1-receptor antagonist) and acts by blocking the action of histamine in the body by competitive reversible blockade of histamine

H1-receptor sites on tissues. Thereby mediates the contraction of smooth muscle and the dilation and increased permeability of the capillaries and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Pharmacokinetic Properties

Absorption: Chlorphenamine maleate is well absorbed from the gastrointestinal tract after oral dosing with extensive first pass effect. The effects develop within 30 minutes, and maximum within 1 to 2 hours and last 4 to 6 hours.

Distribution: It is highly bound to plasma proteins. It is distributed widely in the body. It enters the brain and crosses the placenta. Antihistamines pass into the milk at low concentrations.

Metabolism: The plasma half-life has been estimated to be 12 to 15 hours. Chlorphenamineis metabolised to the monodesmethyl and didesmethyl derivatives.

Excretion: It is slowly excreted via urine and bile. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found in the faeces.

Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

List of Excipients

Microcrystalline Cellulose (PH 102) BP
Croscarmellose sodium USP-NF
Purified Talc BP
Magnesium Stearate

Incompatibilities

Not applicable

Shelf Life

36 Months

Special Precautions for Storage

Do not store above 30°C. Protect from light.

Nature and Contents of Container

10 tablets are packed in Alu-PVC blister pack. Such 1 blister pack is packed in a printed carton with packing insert.

Special precaution for disposal and other handling

No special requirements for disposal.

7. Marketing Authorization Holder and Manufacturing Site Addresses

Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062

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8. Marketing Authorization Number

TAN 21 HM 0058

9. Date of first Authorization of the product

December 24, 2020

10. Date of revision of the text

March, 2021