SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1. Proprietary Name

Chaleate® Tablets

1.2. Strength

Each tablet contains chlorphnamine maleate 4mg.

1.3. Description

Yellow, circular, biconvex tablets, plain on both sides.

2. Qualitative and Quantitative composition

2.1. Qualitative Declaration

Recommended International Non-proprietary name (INN): Chlorphenamine maleate.

2.2. Quantitative Declaration

Each tablet contains Chlorphenamine Maleate BP 4mg ***Excipients with known effects:*** Lactose monohydrate For the full list of excipients see Section 6.1.

3.0 Pharmaceutical form

Tablets for oral administration

1. Clinical Particulars

2. Therapeutic Indications

Chaleate® is used for the symptomatic relief of hypersensitivity reactions including urticaria and angioedema, rhinitis and conjunctivitis. They can also be used to prevent relapses of anaphylaxis. Chlorpheniramine maleate is also used to control the pruritus associated with skin disorders suchas atopic eczema.

Chaleate® is useful in supportive treatment of coughs and the common cold.

3. Posology and method of administration Method

of Administration: Oral

Do not exceed the stated dose or frequency of dosing

Adults and children 12 years and above: 1 tablet 4 to 6 hourly. Maximum daily dose 6

tablets(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 (maximum of 12 mg in 24 hours)

Children aged 6- 12 years: ½ tablet 4 to 6 hourly. Maximum daily dose: 3 tablets (12mg) inany 24 hours.

Not recommended for children under 6 years

4. Contraindications

The tablets are contra-indicated in patients who are hypersensitive to antihistamines or to anyof the tablet ingredients.

The anticholinergic properties of Chlorphenamine are intensified by monoamine oxidaseinhibitors (MAOIs). The tablets are therefore contra-indicated in patients who have beentreated with MAOIs within the last fourteen days.

5. Special Warnings and Precautions for Use

preparations should be used with extreme caution in conditions such as closed- angle glaucoma, urinary retention, prostatic hypertrophy, or pyloroduodenal obstruction. The preparations should also be used with caution in patients with epilepsy, severe cardiovasculardisorders.

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may affect ability to drive or operatemachinery

The effect of alcohol may be increased therefore concurrent use should be avoided

Should not be used with antihistamine containing products, including antihistamine containingcough and cold medicines

Chaleate tablets contains Lactose and Tartrazine: Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose- galactose malabsorption should nottake this medicine. Tartrazine may cause allergic reactions.

6. Interaction with other medicinal products and other forms of Interaction

Antihistamines such as Chlorphenamine may enhance the sedative effects of central nervoussystem depressants including alcohol, barbiturates, hypnotics,

opioid analgesics, anxiolytic sedatives, and neuroleptics. Antihistamines have an additive antimuscarinic action with otherantimuscarinic drugs, such as atropine and tricyclic antidepressants.

7. Pregnancy and Lactation

Pregnancy

There is no adequate data from use of chlorphenamine maleate in pregnant women. The potential risk to human is unknown. Use during third trimester may result in reactions in the new born or premature neonates. Not to be used unless considered essential by a physician.

Lactation

Chlorphenamine 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.

8. Effects on Ability to Drive and Use Machines

CHALEATE preparations may cause drowsiness; patients so affected should not drive or operate machinery. Patients on medication should avoid alcoholic drink since it may potentiatethe sedative effects of Chlorphenamine maleate.

9. Undesirable Effects

Adverse effects of antihistamines include antimuscarinic effects, sedation, somnolence, disturbance in attention, abnormal coordination, dizziness, headache, blurred vision, nausea, drymouth and fatigue

Other effects associated with the oral preparations include gastrointestinal disturbances such as vomiting, diarrhea epigastric pain, hypotension, anorexia, urinary retention, muscle weaknesses, hemolytic anemia, tinnitus, chest tightness and thickening of bronchial secretions.

Children and the elderly are more likely to experience neurological anticholinergic effects

andparadoxical excitation (e.g. increased energy, restlessness and nervousness)

10. Overdose and treatmentSymptoms 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

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If over dosage 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

CHALEATE preparations contain Chlorpheniramine maleate, a potent alkylamine derivativewhich is a H_1-receptor antagonist with some mild sedative effects and anti-muscarinic activity. Chlorpheniramine maleate diminishes/abolishes the main actions of histamine in the body by competitive, reversible blockade of histamine H_1 - receptor sites on tissues.

Chlorphenamine has also anticholinergic activity

Antihistamines act to prevent release of histamine, prostaglandins and leukotrienes and have shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction ofoedema 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 4to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorpheniramine is metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found inthe faeces.

5.3. Preclinical Safety Data

No additional data of relevance.

6. Pharmaceutical Particulars

6.1. List of Excipients

Excipients:
Lactose monohydrate
Microcrystalline cellulose
Potassium sorbate
White corn starch
Povidone K-30
Tartrazine yellow soluble colour
Purified talc
Magnesium stearate
Croscarmellose sodium
Sodium Lauryl Sulphate
Purified water

6.2. Incompatibilities

None.

6.3. Shelf Life

36 months

6.4. Special Precautions for Storage

Do not store above 30°C, Store in the original package for blister packs.

6.5. Nature and Contents of ContainerBLISTER PACKS:

Blisters of 10 tablets, 10 of such blisters are packed in a unit carton with a literature insert.

BULK PACKS:

1000's packed in polythene bags contained in HDPE containers with a literature insert.

6.6. Special precaution for disposal and other handling

Any unused product or waste should be disposed of in accordance with local regulatoryrequirements.

7. Marketing Authorization Holder and Manufacturing Site AddressesMarketing Authorization Holder:

Company Name: Laboratory & Allied Limited
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House,Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi**,**
Country **: Kenya**
Telephone **: +254 20 8040306**
Telefax **: +254 20 8040309**
E-Mail **: info@laballied.com**.

Manufacturing Site Address:
Company Name: Laboratory & Allied Limited
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House,Mombasa Road, P.O. Box 42875 GPO 00100**, Nairobi,**
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Telephone **: +254 20 8040306**
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8. Marketing Authorization Number**: TAN 21 HM 0219**

9. Date of first Registration/ Renewal of the Registration: **3rd June, 2021**

KENYA: 30/07/1995

10. Date of revision of the text:
November 2020