1.4 product information

1.4.1 Prescribing information (Summary of product characteristics)

1. Name of the medicinal product

Chaleate® Tablets

2. Qualitative and quantitative composition

Each tablet contains: Chlorphenamine Maleate BP 4mg and excipients provided in Section 6.1.

3.Pharmaceutical form

Tablet for oral administration

Yellow, circular, biconvex tablets, plain on both sides, packed in blisters of 10 x 10's contained in a unit box and 1000's in HDPE container with literature insert.

4. Clinical particulars

4.1 Therapeutic indications.

Chaleate preparations are used for the symptomatic relief of hypersensitivity reaction including urticarial and angioedema, rhinitis and conjunctivitis. They can also be used to prevent relapses of anaphylaxis.

Chlorphenamine maleate is also used to control the pruritus associated with skin disorders such as atopic eczema.

Chaleate preparations are useful in supportive treatment of coughs and common cold.

4.2 Posology and method of administration

Chaleate tablets and Chaleate syrup are administered orally.

Chaleate tablets are administered at a dose of 4mg every 4 to 6 hours up to a maximum of 24mg daily in adults.

Chaleate syrup is administered to children at the dosage given below; or as directed by the physician.

Age(years)	**Dosage (5mL teaspoonful)**
6-12 years	5mL (2mg) 4 to 6 hourly. Max daily dose 30mL (12mg) in any 24 hours.
2-6 years	2.5mL(1mg) 4 to 6 hourly. Max daily dose 15mL (6mg) in any 24hours
1-2 years	2.5ml(1mg) twice daily. Max daily dose 5mL (2mg) in any 24 hours
Not recommended for children below 1 year.	

4.3 Contraindications

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

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

4.4 Special warnings and precautions for use.

1.CHALEATE preparations should not be administered to premature infants or neonates because they have increased susceptibility to antimuscarinic effects. Elderly patients are also more susceptible to many adverse effects of antihistamines including antimuscarinic effects, sedation, and hypotension thus the preparations should be given with caution to such patients

2.CHALEATE® preparations should also be used with extreme caution in conditions such as closed-angle glaucoma, urinary retention. Prostatic hypertrophy or pyloroduodenal obstruction. The preparations should be used with caution in patients with epilepsy, severe cardiovascular disorders and pregnant patients especially during the first trimester.

3.CHALEATE® preparations may cause drowsiness; patients so affected should not drive or operate machinery. Patients on medication should avoid alcoholic drinks since alcohol may potentiate the sedative effects of chlorphenamine maleate.

4.The adverse effects associated with the oral preparations include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or epigastric pain. Other adverse effects associated with Chlorphenamine preparations include antimuscarinic effects, CNS stimulation, extrapyramidal symptoms and hypersensitivity reactions including photosensitivity, transitory hypotension and CNS stimulation.

4.5 Interaction with other medicinal products and other forms of interaction

Antihistamines such as Chlorphenamine may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and neuroleptics. Antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and tricyclic antidepressants.

4.6 Pregnancy and lactation

Chaleate should be used with caution pregnant patients especially during the first trimester. CHALEATE® preparations should not be administered to premature infants or neonates because they have increased susceptibility to antimusarinic effects.

4.7 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 potentiate the sedative effects of Chlorphenamine maleate.

4.8 Undesirable effect

The following effects have been reported and are listed below by system organ class:

System Organ Class (SOC)	**Frequency**	**Adverse Event**
Blood and lymphatic system disorders	Not known*	Haemolytic anaemia and other blood dyscrasias
Cardiac disorders	Not known*	Palpitations
Ear and labyrinth disorders	Not known*	Tinnitus
Eye disorders	Not known*	Blurred vision
Gastrointestinal disorders	Not known*	Nausea, vomiting, diarrhoea, dry mouth, painful dyspepsia
General disorders and administration site conditions	Not known*	Irritability, lassitude, stinging or burning sensation at the site of injection
Hepatobiliary disorders	Not known*	Hepatitis including jaundice
Immune system disorders	Not known*	Hypersensitivity, anaphylactic reaction
Metabolism and nutrition disorders	Not known*	Anorexia
Musculoskeletal and connective tissue disorders	Not known*	Twitching, muscular weakness, incoordination
Nervous system disorders	Not known*	Headaches, dizziness, inability to concentrate, sedation (most common side effect varying from slight drowsiness to deep sleep), CNS stimulation (as a result of rapid intravenous injection)
Psychiatric disorders	Not known*	Depression, nightmares, paradoxical excitation in children, confusional psychosis in the elderly
Renal and urinary disorders	Not known*	Urinary retention
Respiratory, thoracic and mediastinal disorders	Not known*	Thickening of bronchial secretions
Skin and subcutaneous tissue disorders	Not known*	Exfoliative dermatitis, photosensitivity, skin reactions, urticaria
Vascular disorders	Not known*	Transitory hypotension (as a result of rapid intravenous injection)

*** Cannot be estimated from the available data**

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.

4.9 Overdose and treatment

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

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.e., diazepam. Hemoperfusion may be used in severe cases.

5. Pharmacological properties

5.1 Pharmacodynamic properties

CHALEATE® preparations contain Chlorpheniramine maleate, a potent alkylamine derivative which is a H1-receptor antagonist with some mild sedative effects and anti-muscarinic activity. Chlorpheniramine maleate in the preparations diminishes/abolishes the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues without inactivating histamine or preventing its release or synthesis. This effect leads to vasodilation, increased capillary permeability, flare and itch reactions on the skin, some extent of contraction of smooth muscle in the bronchi and gastro-intestinal tract.

5.2 Pharmacokinetic properties

CHALEATE® preparations contain Chlorpheniramine maleate, a potent alkylamine derivative which is a H1-receptor antagonist with some mild sedative effects and anti-muscarinic activity. Chlorpheniramine maleate in the preparations diminishes/abolishes the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues without inactivating histamine or preventing its release or synthesis. This effect leads to vasodilation, increased capillary permeability, flare and itch reactions on the skin, some extent of contraction of smooth muscle in the bronchi and gastro-intestinal tract.

5.3 Preclinical data safety

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Lactose Monohydrate
White Corn Starch
Microcrystalline Cellulose (pH 101)
Potassium Sorbate
Povidone K-30
Tartrazine Yellow Soluble Colour
Purified Water
Croscarmellose Sodium
Sodium Lauryl Sulfate
Purified Talc
Magnesium Stearate
Sodium Benzoate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage
Store in a dry place below 30°C.
Protect form light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container
Yellow, Circular biconvex tablets plain on both sides. Packed in blisters of 10x10's in a unit box,1000's in HDPE container with literature insert.
6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LTD
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 LTD
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

8. Marketing Authorization Number:
Kenya: H95/099

9. Date of first Registration/ Renewal of the Registration:
Kenya: 07/30/1995

10. Date of revision of the text:
June 2023.