SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name : **Cipium Tablet**
1.2 Generic Name : Chlorpheniramine Tablets BP 4 mg
1.3 Strength : Chlorpheniramine BP 4mg/Tab.
1.4 Pharmaceutical Form : Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each uncoated tablet contains:
Chlorpheniramine Maleate BP 4 mg

3. PHARMACEUTICAL FORM

Tablet

White coloured round shaped biconvex uncoated tablet, having central break line on one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorpheniramine (Cipium) is indicated for the symptomatic relief of allergy such as hay fever, urticaria, food allergy, drug reactions, relief of itch associated with chickenpox.

4.2 Posology and method of administration

Symptomatic relief of allergy such as hay fever, urticaria, food allergy, drug reactions, relief of itch associated with chickenpox:

Child 12–23 months: 1 mg twice daily.
Child 2–5 years: 1 mg every 4–6 hours; maximum 6 mg per day.
Child 6–11 years: 2 mg every 4–6 hours; maximum 12 mg per day.

Child 12–17 years: 4 mg every 4–6 hours; maximum 24 mg per day.
Adult: 4 mg every 4–6 hours; maximum 24 mg per day.
Elderly: 4 mg every 4–6 hours; maximum 12 mg per day.

4.3 Contraindications

Many antihistamines should be avoided in acute porphyrias but Chlorpheniramine is thought to be safe. Sedating antihistamines have significant antimuscarinic activity and they should therefore be used with caution in prostatic hypertrophy, urinary retention, susceptibility to angle-closure glaucoma, and pyloroduodenal obstruction.

4.4 Special warnings and special precautions for use

Caution may be required in epilepsy prostatic, hypertrophy, pyloroduodenal obstruction, susceptibility to angle-closure glaucoma, urinary retention.

MHRA/CHM Advice: Children less than 6 years should not be given over-the counter cough and cold medicines Containing chlorpheniramine.

Hepatic Impairment: Sedating antihistamines should be avoided in severe liver disease-increased risk of coma.

4.5 Interaction with other FPPs and Other forms of Interaction

Plasma concentration of Chlorpheniramine possibly increased by lopinavir, Increased sedative effect when alcohol, opioid analgesics, MAOI's or tricyclics, anxiolytics, hypnotics, are given with antihistamines, increased risk of antimuscarinic side effects when antihistamines given with antimuscarnics. Antihistamines therotically antagonize the effect of histamine, betahistine. Increased antimuscarinic and sedative effects when tricyclics related antidepressants given with antihistamines.

4.6 Pregnancy and lactation

Pregnancy: Avoid the use of antihistamines during pregnancy; however, there is no evidence of teratogenicity except for hydroxyzine where toxicity has been reported with high doses in animal studies. Use in the latter part of the third trimester may cause adverse effects in neonates such as irritability, paradoxical excitability and tremor.

Lactation: Most antihistamines are present in breast milk in varying amounts: although not known to be harmful, hence it advises to avoid the use of anti-histamines in mothers who are breast-feeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Common or very common: Blurred vision, dry mouth, gastro-intestinal disturbances, headache, psychomotor, impairment and urinary retention.

Rare: anaphylaxis, angioedema, angle-closure glaucoma (in adults), arrhythmias, bronchospasm, confusion, convulsions, depression, dizziness, extrapyramidal, effects, hypersensitivity reactions, hypotension, liver dysfunction, palpitation, photosensitivity reactions, sleep disturbances, tremor.

Frequency not known: Anti-muscarinic effects: Blood disorders, exfoliative dermatitis, rashes tinnitus.

4.9 Overdose & Treatment

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamine (H1 antagonist)

Mechanism of action:

Chlorpheniramine, is a histamine H1 antagonist, it competes with histamine for the normal H1-receptor sites on effector cells of the gastrointestinal tract, blood vessels and respiratory tract. Allergic reactions release histamine, acting on H1-receptors, produces pruritus, vasodilatation, hypotension, flushing, headache, tachycardia, and bronchoconstriction. It also increases vascular permeability and potentiates pain.

5.2 Pharmacokinetic properties

Chlorpheniramine Maleate is well absorbed in the gastrointestinal tract. It shows approximately 69–72% protein binding. It undergoes rapid and extensive distribution; Metabolism -primarily hepatic via Cytochrome P450 (CYP450) enzymes. It is excreted in urine.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Starch (Maize)	BP
02.	Calcium Hydrogen Phosphate	BP
03.	Lactose	BP
04.	Microcrystalline Cellulose	BP
05.	Propyl Hydroxybenzoate (Propylparaben)	BP
06.	Gelatin	BP
07.	Purified Talc (Talcum)	BP
08.	Magnesium Stearate	BP
09.	Colloidal Anhydrous Silica (Colloidal Silicone Dioxide)	BP
10.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of children. Keep away from moisture.

6.5 Nature and contents of container

a. 10 blisters of 20 (i.e. 10's x 2) tablets packed in an inner carton. (20x10)
b. 10 blisters of 10 tablets packed in an inner carton. (10's x 10)
c. 25 blisters of 20 (i.e. 10's x 2) tablets packed in an inner carton. (20's x 25)
d. 50 blisters of 20 (i.e. 10's x 2) tablets packed in an inner carton. (20's x 50)
e. 1000 tablets packed in a white coloured HDPE jar. (1000's)

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

06903/08244/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT

01/01/2023