

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-LORATADINE (Tablets)

COMPOSITION:

Each CIPLA-LORATADINE tablet contains 10 mg loratadine (micronised).

PHARMACOLOGICAL CLASSIFICATION:

A.5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:

Loratadine is a second generation histamine (H₁)-receptor antagonist. Loratadine exerts its action by competing with histamine for H₁-receptor sites on effector cells. It prevents, but does not reverse, responses mediated by histamine. Loratadine does not cross the blood-brain barrier to any extent.

Pharmacokinetics:

After oral administration, loratadine is well absorbed from the gastrointestinal tract and peak plasma concentrations are reached within 1.5 hours. Ingestion of food may enhance the absorption of loratadine. Loratadine undergoes extensive first pass metabolism via the cytochrome P450 system.

The major metabolite, desloratadine, is active. Loratadine is 97 % protein bound, while desloratadine is less extensively protein bound (73 % to 77 %). The mean elimination half-lives for loratadine and desloratadine are 8.4 and 28 hours, respectively.

INDICATIONS:

CIPLA-LORATADINE is indicated for the symptomatic relief of seasonal allergic rhinitis and chronic urticaria.

CONTRA-INDICATIONS:

- Hypersensitivity to CIPLA-LORATADINE or to any of the ingredients in the preparation.
- Cross-sensitivity to other antihistamines.
- Porphyria.

WARNINGS:

Safety of CIPLA-LORATADINE in the elderly has not been established. Safety of CIPLA-LORATADINE in children under two years of age has not been established.

CIPLA-LORATADINE should be used with caution in patients with:

- Severe liver impairment, as reduced clearance of loratadine may occur. Dosage adjustment may be needed (see "DOSAGE AND DIRECTIONS FOR USE").
- Renal impairment – A lower starting dose should be used. In patients with chronic renal impairment (creatinine clearance of 30 ml/minute or less), both oral bioavailability and peak plasma concentrations of loratadine may be increased. However, the elimination half-lives of loratadine and its active metabolite appear to be similar to those in individuals with normal renal function.

CIPLA-LORATADINE may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other nervous system depressants (e.g., sedatives and tranquilisers). Caution should be used when driving a motor vehicle or operating machinery or performing potentially dangerous tasks, where loss of concentration may lead to accidents.

INTERACTIONS:

Concomitant use of CIPLA-LORATADINE with inhibitors of the cytochrome P450 enzyme system, such as cimetidine, ketoconazole, clarithromycin and erythromycin, may increase the plasma concentration of CIPLA-LORATADINE.

PREGNANCY AND LACTATION:

Safety and efficacy in pregnancy and lactation have not been established. Loratadine and its metabolites have been detected in breast milk. Small amounts of CIPLA-LORATADINE entering breast milk may cause drowsiness or excitement in infants.

DOSAGE AND DIRECTIONS FOR USE:

Children 2 to 12 years of age:

Body weight less than or equal to 30 kg: 5 mg (½ tablet) once daily.
Body weight more than 30 kg: 10 mg (1 tablet) once daily.

Adults and children over 12 years of age:

10 mg (1 tablet) once daily.

Adults with severe liver function impairment:

Initial dose is 5 mg (½ tablet) once daily or 10 mg (1 tablet) on alternate days.

Use of CIPLA-LORATADINE should be limited to 14 days.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Immune system disorders:

Less frequent: Allergic reactions, anaphylaxis.

Neuropsychiatric system disorders:

Frequent: Headache, somnolence, nightmares.

Less frequent:

Sedation, nervousness, confusion, fatigue, convulsions, increased appetite or loss of appetite, abnormal coordination, and tremor.

Disorders of the special senses:

Less frequent: Ringing or buzzing in the ears and blurred vision.

Cardiovascular system disorders:

Less frequent: Cardiac arrhythmias, palpitations, tachycardia, and oedema.

Gastrointestinal system disorders:

Frequent: Dry mouth, gastrointestinal disorders, such as nausea and gastritis.

Less frequent:

Constipation, diarrhoea.

Hepatobiliary system disorders:

Less frequent: Abnormal hepatic function, hepatitis or cholestasis.

Skin and subcutaneous tissue disorders:

Less frequent: Rash, increased sweating, photosensitivity.

The following side-effects have been reported and frequencies are unknown: Alopecia.

Renal and urinary system disorders:

Less frequent: Difficult or painful urination.

Reproductive system and breast disorders:

Less frequent: Early menses.

Special Precautions:

CIPLA-LORATADINE should be discontinued prior to skin tests using allergen extracts, as it may inhibit the cutaneous histamine response, thus producing false-negative results.

CIPLA-LORATADINE should be discontinued at least 48 hours before such tests.

CIPLA-LORATADINE should be used with caution in patients using other medication metabolised by the cytochrome P450 system and/or when the following medical conditions exist:

- Emphysema, prostatic hypertrophy, narrow-angle glaucoma, cardiovascular disorders, epilepsy and during acute attacks of asthma.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

(See "SIDE-EFFECTS AND SPECIAL PRECAUTIONS").

Symptoms of overdose:

Tachycardia, somnolence and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment of overdose:

Treatment is symptomatic and supportive. After overdose of CIPLA-LORATADINE, the stomach should be emptied immediately by inducing emesis or by gastric lavage. Administration of activated charcoal after emesis may be useful in preventing absorption of CIPLA-LORATADINE. Saline cathartics may be of value to rapidly dilute bowel contents. CIPLA-LORATADINE is not cleared by haemodialysis.

IDENTIFICATION:

White, circular, flat, bevelled tablets, with a breakline on one side and plain on the other side.

PRESENTATION:

Blister packs of 7, 10, 30 and 250 tablets.

STORAGE INSTRUCTIONS:

Store below 25°C. Protect from moisture.

Keep the blister strips in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

A38/5.7.1/0491.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE

CERTIFICATE OF REGISTRATION:

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