1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

AP-LORATADINE 10 mg TABLET

COMPOSITION

Each tablet of AP-LORATADINE 10 mg TABLET contains 10 mg of loratadine

Excipients:

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maize starch, purified talc, sodium starch glycollate.

Contains sugar: Lactose monohydrate 77,0 mg

CATEGORY AND CLASS

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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.

Pharmacokinetic properties

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 P-450 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

AP-LORATADINE 10 mg TABLET is indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRAINDICATIONS

Hypersensitivity to AP-LORATADINE 10 mg TABLET or to any ingredients of this preparation.

Cross sensitivity to other antihistamines.

Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS

Safety of AP-LORATADINE 10 mg TABLET in the elderly has not been established.

Safety of AP-LORATADINE 10 mg TABLET in children under two years of age has not been established.

AP-LORATADINE 10 mg TABLET 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-life of loratadine and its active metabolite appear to be similar to those individuals with normal renal function.

AP-LORATADINE 10 mg TABLET lacks significant sedative effects.

AP-LORATADINE 10 mg TABLET should be discontinued prior to skin tests using allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results.

AP-LORATADINE 10 mg TABLET should be discontinued at least 48 hours before the test.

AP-LORATADINE 10 mg TABLET should be used with caution when the following medical conditions exist and/or in patients using other medication metabolised by the cytochrome P-450 system:
Emphysema; prostatic hypertrophy; narrow angle glaucoma; cardiovascular disorder; epilepsy; and during acute attacks of asthma.

Excipients

Lactose warning:

AP-LORATADINE 10 mg TABLET contains lactose/fructose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take AP-LORATADINE 10 mg TABLET.

INTERACTIONS

Concomitant use of AP-LORATADINE 10 mg TABLET with:

- Inhibitors of cytochrome P-450 enzyme system such as cimetidine, ketoconazole, clarithromycin and erythromycin may increase the plasma concentration of AP-LORATADINE 10 mg TABLET.

HUMAN REPRODUCTION

Safety and efficacy in pregnancy and lactation have not been established. AP-LORATADINE 10 mg TABLET and its metabolites have been detected in breast milk. Small amounts of AP-LORATADINE 10 mg TABLET entering breast milk may cause drowsiness or excitement in the infant.

DOSAGE AND DIRECTIONS FOR USE

Adults: one tablet a day.

Adults with severe liver function impairment: initial dose is 5 mg once daily or 10 mg on alternate days.

Use of AP-LORATADINE 10 mg TABLET should be limited to 14 days.

SIDE EFFECTS

Central nervous system:

Frequent: Fatigue, headache, somnolence, blurred vision, confusion, nightmares

Less frequent: Sedation, nervousness

Gastrointestinal:

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

Liver:

Less frequent: Abnormal hepatic function

Skin:

Less frequent: Rash, alopecia

Other:

Less frequent: Allergic reactions, anaphylaxis

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Somnolence; tachycardia; and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment

Treatment is symptomatic and supportive. After overdose of AP-LORATADINE 10 mg TABLET, 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 AP-LORATADINE 10 mg TABLET. Saline cathartics may be of value to rapidly dilute bowel contents. AP-LORATADINE 10 mg TABLET are not cleared by haemodialysis.

IDENTIFICATION

A white, oval, biconvex tablet bisected on one side.

PRESENTATION

AP-LORATADINE 10 mg TABLET is packed as follows:

- 10 tablets are packed into either polyvinyl chloride/polyvinylidene chloride (clear or red) or polyvinyl chloride/polyethylene/polyvinylidene chloride (bluish in appearance characterized by excellent transparency) blister strips sealed with printed aluminum foil. Each blister strip contains 10 tablets. The blister strips are placed into an outer cardboard carton together with a leaflet.
- 30 tablets are packed into either polyvinyl chloride/polyvinylidene chloride (clear or red) or polyvinyl chloride/polyethylene/polyvinylidene chloride (bluish in appearance characterized by excellent transparency) blister strips sealed with printed aluminum foil. Each blister strip contains 10 tablets or 15 tablets. The blister strips are placed into an outer cardboard carton together with a leaflet.
- 100 tablets are packed into a white polypropylene securitainer, with a white foam insert, a leaflet and sealed with a white low-density polyethylene tamper-proof snap-on cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Store in a dry place.

Keep the container tightly closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

35/5.7.1/0084

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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