## 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

## SCHEDULING STATUS

**S1**

## PROPRIETARY NAME AND DOSAGE FORM

**AP LORATADINE SYRUP**

## COMPOSITION

Each 5 ml of AP LORATADINE SYRUP contains 5 mg of loratadine.

*Excipients:*

Flavour blackcurrant, glycerol, hydroxyethylcellulose, polysorbate, propylene glycol, purified water, sodium benzoate, sodium cyclamate, sorbitol (70 %) solution

*Preservative:*

Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol (70 %) solution 0,75 ml

Contains sweetener: Sodium cyclamate 62,50 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 SYRUP is indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic urticaria.

**CONTRAINDICATIONS**

Hypersensitivity to AP LORATADINE SYRUP or to any ingredients of this preparation.

Cross sensitivity to other antihistamines.

Porphyria.

**WARNINGS AND SPECIAL PRECAUTIONS**

Safety of AP LORATADINE SYRUP in the elderly has not been established.

Safety of AP LORATADINE SYRUP in children under two years of age has not been established.

AP LORATADINE SYRUP 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 SYRUP lacks significant sedative effects.

AP LORATADINE SYRUP 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 SYRUP should be discontinued at least 48 hours before the test.

AP LORATADINE SYRUP 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*

Contains sorbitol solution which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary condition of sorbitol intolerance should not take AP LORATADINE SYRUP.

**INTERACTIONS**

Concomitant use of AP LORATADINE SYRUP with:

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

**HUMAN REPRODUCTION**

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

**DOSAGE AND DIRECTIONS FOR USE**

Shake well before use.

**Children 2 to 12 years of age:**

Body weight less than or equal to 30 kg: 5 mg once daily.

Body weight more than 30 kg: 10 mg once daily.

**Adults and children over 12 years of age:** 10 mg once daily.

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

Use of AP LORATADINE SYRUP should be limited to 14 days.

**SIDE EFFECTS**

**Frequently occurring:**

**Nervous system disorders**

- Fatigue
- Headache
- Somnolence
- Blurred vision
- Confusion
- Nightmares

**Gastrointestinal disorders**

- Dry mouth
- Nausea
- Gastritis

**Less-frequently occurring:**

**Nervous system disorders**

- Sedation
- Nervousness

**Hepatobiliary disorders**

- Abnormal hepatic function

**Skin and subcutaneous tissue disorders**

- Rash
- Alopecia

**Immune system disorders**

- 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 SYRUP, 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 SYRUP. Saline cathartics may be of value to rapidly dilute bowel contents. AP LORATADINE SYRUP is not cleared by haemodialysis.

## IDENTIFICATION

A clear, colourless to light yellow solution with a blackcurrant odour.

## PRESENTATION

150 ml are packed into a round, amber glass bottle and sealed with a white, polypropylene cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

**STORAGE INSTRUCTIONS**

Store at or below 25 °C in tightly closed containers.

Protect from light.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

**REGISTRATION NUMBER**

38/5.7.1/0083

**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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Date of the most recent amendment to the professional information as approved by the Authority: 29 July 2005

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