PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CLARITYNE™ Syrup

COMPOSITION

Active ingredients: 5 mg of loratadine (micronized).

Inactive ingredients: Citric acid monohydrate, glycerol, propylene glycol, sucrose, peach flavour and purified water.

Preservative: Sodium benzoate 0,1 % m/v.

Contains sugar(s): Sucrose 3,0 g

CATEGORY AND CLASS

A.5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION

Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H_1-receptor antagonistic activity. Loratadine does not readily cross the blood-brain barrier.

Loratadine undergoes rapid hepatic metabolism to an active metabolite, desloratadine. Maximal serum levels were achieved within 1,5 hours. Clinical effect was achieved within two hours. Excretion occurred equally via renal and faecal routes.

PROFESSIONAL INFORMATION

INDICATIONS

CLARITYNE™ Syrup is indicated for the relief of symptoms associated with allergic rhinitis, chronic urticaria and other allergic skin disorders.

CONTRAINDICATIONS

CLARITYNE™ Syrup is contraindicated in patients who have shown sensitivity or idiosyncrasy to any of the components.

Children under two years of age as safety has not been established.

Safety of **CLARITYNE™ Syrup** in the elderly has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Patients with liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. Therefore, the following dosing is recommended: one half the recommended dose every day or the full recommended dose every other day.

Special Precautions

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of 5 ml once daily, or 10 ml every other day is recommended.

Efficacy of **CLARITYNE™ Syrup** has not yet been established in children younger than 2 years of age. However, the pharmacokinetic profile of loratadine in infants 1 to 2 years after the administration of a single 2,5 mg dose of **CLARITYNE™ Syrup** is similar to that in older children and adults.

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

PROFESSIONAL INFORMATION

CLARITYNE™ Syrup contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take **CLARITYNE™ Syrup**.

Effects on Ability to Drive and Use Machines:

CLARITYNE™ Syrup lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

INTERACTIONS

The use of **CLARITYNE™ Syrup** should be discontinued approximately 48 hours prior to skin testing procedures since **CLARITYNE™ Syrup** may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials. Other medicines known to inhibit hepatic metabolism should be co-administered with caution in the absence of formal interaction studies.

HUMAN REPRODUCTION

The safe use of **CLARITYNE™ Syrup** in pregnant or mothers who are breastfeeding their infants have not been established.

PROFESSIONAL INFORMATION

DOSAGE AND DIRECTIONS FOR USE

Children 2 to 12 years of age*:*

Body Weight equal to or less than 30 kg: 5 ml (1 medicine measure) once daily.

Body Weight more than 30 kg: 10 ml (2 medicine measures) once daily.

Adults and Children 12 years of age and over:

10 ml (2 medicine measures) once daily.

SIDE-EFFECTS

Table 1: The following side-effects have been reported and the frequencies are unknown	
Immune system disorders	Anaphylaxis including angioedema
Nervous system disorders	Headache, somnolence, sedation, nervousness, dizziness, convulsion
Cardiac disorders	Palpitations, tachycardia
Gastrointestinal disorders	Nausea, gastritis, dry mouth
Hepatobiliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administrative site conditions	Fatigue

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Refer to “Side-Effects”.

Overdosage Information: Somnolence, tachycardia and headache have been reported with overdoses. In the event of overdosage, treatment should be started immediately.

PROFESSIONAL INFORMATION

Treatment: Treatment is symptomatic and supportive. Consider standard measures to remove any unabsorbed drug in the stomach, such as adsorption by activated charcoal administered as a slurry with water. The administration of gastric lavage should be considered. 0,9 % Sodium chloride solution is the lavage solution of choice, particularly in children. In adults, tap water can be used; however, as much as possible of the amount administered should be removed before the next instillation. Sodium chloride cathartics draw water into the bowel by osmosis and, therefore, may be valuable for their action in rapid dilution of bowel content. Loratadine is not cleared by haemodialysis to any appreciable extent. After emergency treatment, the patient should continue to be medically monitored.

IDENTIFICATION

Clear, colourless to light-yellow syrup, with a characteristic peach odour and flavour, and free from foreign matter.

PRESENTATION

Bottles of 50 ml, 100 ml and 150 ml.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep out of reach of children.

REGISTRATION NUMBER

Z/5.7.1/56

PROFESSIONAL INFORMATION

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

Bayer (Pty) Ltd

27 Wrench Road

Isando

1600

SOUTH AFRICA

1968/011192/07

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Date on the registration certificate: 15 January 1992

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Manufactured by Schering-Plough Labo N.V., Belgium for Bayer (Pty) Ltd.