PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CLARITYNE™ TABLETS

COMPOSITION

Each CLARITYNE TABLET contains 10 mg loratadine (micronized).

Inactive ingredients: Lactose, magnesium stearate, maize starch and purified water.

Contains sugar: Lactose 71,3 mg

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.

Maximal serum levels were achieved within 1.5 hours. Clinical effect was achieved within 2 hours. Excretion occurred equally via renal and faecal routes.

INDICATIONS

CLARITYNE TABLETS are indicated for the relief of the symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRAINDICATIONS

CLARITYNE TABLETS are contraindicated in patients who have shown sensitivity or idiosyncrasy to its components.

PROFESSIONAL INFORMATION

Safety of CLARITYNE TABLETS in the elderly has not been established.

WARNINGS and SPECIAL PRECAUTIONS

Patients with severe liver impairment should receive a lower initial dose because they may have a reduced clearance of loratadine i.e. an initial dose of 5 mg once daily, or 10 mg every other day is recommended.

Special Precautions

CLARITYNE TABLETS lack significant sedative effects. However, patients should 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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take CLARITYNE TABLETS.

INTERACTIONS

CLARITYNE TABLETS should be discontinued approximately 48 hours prior to skin testing procedures since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

An increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic). Other medicines known to inhibit hepatic metabolism should be co-administered with caution together with CLARITYNE TABLETS until definitive interaction studies can be completed.

HUMAN REPRODUCTION

The safe use of CLARITYNE TABLETS during pregnancy or lactation has not been established.

PROFESSIONAL INFORMATION

DOSAGE AND DIRECTIONS FOR USE

Adults: One CLARITYNE TABLET once daily.

SIDE EFFECTS

In clinical trials involving adults and adolescents in a range of indications including allergic rhinitis and chronic iodiopathic urticaria, at the recommended dose of 10 mg daily, side effects with CLARITYNE TABLETS were reported in 2 % of patients in excess of those treated with placebo. The most frequent side effects reported in excess of placebo were somnolence (1.2 %), headache (0.6 %), increased appetite (0.5 %) and insomnia (0.1 %).

Other side effects reported during post-marketing period are listed in the following table.

Immune system disorders	Anaphylaxis including angioedema
Nervous system disorders	Dizziness, convulsion
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders	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 medicine 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. Saline cathartics draw water into the bowel by osmosis and therefore, may be valuable for their action in rapid dilution of bowel content. CLARITYNE TABLETS are not cleared by haemodialysis to any appreciable extent. After emergency treatment, the patient should continue to be medically monitored.

IDENTIFICATION

Oval, convex, white tablet, scored on one side with the trademark above the score, and the number 10 below the score.

PRESENTATION

Blister packs of-10, 30 tablets.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Do not freeze. Protect from moisture.

Keep out of reach of children.

REGISTRATION NUMBER

U/5.7.1/27

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

Bayer (Pty) Ltd,

27 Wrench Road, Isando, 1600

PROFESSIONAL INFORMATION

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION

Date on the registration certificate: 03 October 1990

Date of the most recently approved professional information: 11 December 2013

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