

Applicant/ PHCR: Bayer (Pty) Ltd
Product Name: Clarityne
Dosage Form and Strength: Syrup, 5 mg loratadine per 5 ml & Tablets, 10 mg Loratadine

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CLARITYNE™ Syrup, (Syrup)

CLARITYNE™ Tablets, (Tablet)

COMPOSITION

CLARITYNE™ Syrup per 5 ml:

Active ingredients: 5 mg of loratadine (micronized).

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

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

Contains sugar: Sucrose. 3.0 g

CLARITYNE™ Tablets per tablet:

Active ingredient: 10 mg loratadine (micronized).

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

Contains sugar: Lactose monohydrate 0.071 g/tablet

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CATEGORY AND CLASS:

A.5.7.1 Antihistaminics

Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H₁-receptor antagonistic activity. Loratadine does not readily cross the blood-brain barrier.

Loratadine undergoes rapid hepatic metabolism to an active metabolite, desloratadine.

PHARMACOLOGICAL ACTION

Maximal serum levels were achieved within 1,5 hours. Clinical effect was achieved within two hours. Excretion occurred equally via renal and faecal routes.

INDICATIONS

CLARITYNE™ is indicated for the relief of symptoms associated with perennial and /or seasonal allergic rhinitis, chronic urticaria and other allergic skin disorders

CONTRAINDICATIONS

CLARITYNE™ is contraindicated in patients who have shown sensitivity or idiosyncrasy to its components.

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

CLARITYNE™ is contraindicated in children under two years of age as safety has not been established.

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WARNINGS AND SPECIAL PRECAUTIONS

Patients with severe liver impairment should be administered a lower initial dose of **CLARITYNE™** because they may have a reduced clearance of loratadine; an initial dose of 5 ml (or 5 mg tablet) once daily, or 10 ml (or 10 mg tablet) 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.

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

Weight gain has been reported with the use of loratadine, but the frequency is unknown.

Effects on Ability to Drive and Use Machines:

CLARITYNE™ 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

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compounded by the simultaneous intake of alcohol or other central nervous system depressants.

INTERACTIONS

Medicine/laboratory test interactions

The use of **CLARITYNE™** 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™** until definitive interaction studies can be completed or in the absence of formal interaction studies.

HUMAN REPRODUCTION

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

DOSAGE AND DIRECTIONS FOR USE

For oral use only.

CLARITYNE™ can be taken with or without meal.

CLARITYNE™ Syrup:

Children 2 to 12 years of age:

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

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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.

CLARITYNE™ Tablets:

Adults: One tablet once daily.

SIDE-EFFECTS

In clinical trials involving adults and adolescents in a range of indications including allergic rhinitis and chronic idiopathic 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.

<i>Immune system disorders</i>	Anaphylaxis including angioedema
<i>Metabolism and nutrition disorders</i>	Increased appetite
<i>Nervous system disorders</i>	Headache, somnolence, sedation, nervousness, Dizziness, convulsion
<i>Cardiac disorders</i>	Tachycardia, palpitation
<i>Gastrointestinal disorders</i>	Nausea, dry mouth, gastritis
<i>Hepatobiliary disorders</i>	Abnormal hepatic function
<i>Skin and subcutaneous tissue disorders</i>	Rash, alopecia

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<i>General disorders and administrative site conditions</i>	Fatigue
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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.

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. Sodium chloride or saline 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

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

CLARITYNE™ Tablets: Oval, convex, white tablet, scored on one side with the trademark above the score, and the number 10 below the score

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PRESENTATION

CLARITYNE™ Syrup: Bottles of 100 ml

CLARITYNE™ Tablets: Blister packs of 10 and 30 tablets

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Do not freeze.

Keep out of reach of children.

CLARITYNE™ Tablets: Protect from moisture

REGISTRATION NUMBER

CLARITYNE™ Syrup: Z/5.7.1/56

CLARITYNE™ Tablets: U/5.7.1/27

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

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DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION:

CLARITYNE™ Syrup:

Date on the registration certificate: 15 January 1992

Date of most recently revised professional information: 31 October 2018

CLARITYNE™ Tablets:

Date on the registration certificate: 03 October 1990

Date of most recently revised professional information: 31 October 2018

	Clarityne Tablets	Clarityne Syrup
	Registration Number/ Scheduling Status	Registration Number/Scheduling Status
Botswana only	BOT1302271/A/B (S3)	BOT0400655 (S2)
Namibia only	06/5.7.1/0046 (NS1)	10/5.7.1/0103 (NS1)