PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINAL PRODUCT

CLARITYNE™ Syrup, 1 mg/ml

CLARITYNE™ Tablets, 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CLARITYNE™ Syrup per 5 ml:

Active ingredients: 5 mg of loratadine (micronized).

Excipients with known effect:

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

Contains sugar**:** Sucrose. 3.0 g

For full list of excipients, see section 6.1

CLARITYNE™ Tablets per tablet:

Active ingredient: 10 mg loratadine (micronized).

Excipients with known effect:

Contains sugar: Lactose monohydrate 0.071 g/tablet

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

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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4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

4.2. Posology and method of administration

Posology

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.

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.

Special Populations

Elderly population

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

Patients with hepatic impairment

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

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Paediatric population

The safety and efficacy of CLARITYNE™ in children under 2 years of age have not been established. No data are available

Method of administration

For oral use only. CLARITYNE™ can be taken with or without meal.

4.3. 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.

4.4. Special warnings and precautions for use

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.

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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.

4.5. Interaction with other medicinal products and other forms of interaction

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.

4.6. Fertility, pregnancy and lactation

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

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

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4.8. Undesirable effects

a) Summary of the safety profile

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 %)

b) Tabulated summary of adverse reactions

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

Immune system disorders	Anaphylaxis including angioedema
Metabolism and nutrition disorders	Increased appetite
Nervous system disorders	Headache, somnolence, sedation, nervousness, 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 and administrative site conditions	Fatigue

Reporting of suspected adverse reactions

Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form",** found under SAHPRA's publications: Https://www.sahpra.org.za/Publications/Index/8.

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4.9. Overdose

Refer to “4.8 Undesirable 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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A.5.7.1 Antihistaminics

Mechanism of 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.

5.2. Pharmacokinetic properties

Absorption and Distribution

Maximal serum levels were achieved within 1,5 hours. Clinical effect was achieved within two hours.

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Biotransformation

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

Elimination

Excretion occurred equally via renal and faecal routes.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

CLARITYNE ™ Syrup

Citric acid monohydrate,

Glycerol,

Peach flavor,

Propylene glycol,

Purified water

Sucrose.

CLARITYNE™ Tablets

Lactose monohydrate,

Magnesium stearate,

Maize starch

Purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

CLARITYNE ™ Syrup: 36 months

CLARITYNE™ Tablets: 48 months

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6.4. Special Precautions for storage

Store at or below 25 °C.

Do not freeze.

CLARITYNE™ Tablets:

Protect from moisture

6.5. Nature and contents of container

CLARITYNE™ Syrup: Bottles of 100 ml

CLARITYNE™ Tablets: Blister packs of 10 and 30 tablets

6.6. Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

27 Wrench Road

Isando, 1600

SOUTH AFRICA

1968/011192/07

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8. REGISTRATION NUMBER(S)

CLARITYNE™ Syrup: Z/5.7.1/56

CLARITYNE™ Tablets: U/5.7.1/27

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

CLARITYNE™ Syrup: Date on the registration certificate: 15 January 1992

CLARITYNE™ Tablets: Date on the registration certificate: 03 October 1990

PROPOSED PROFESSIONAL INFORMATION

10. DATE OF REVISION OF THE TEXT

CLARITYNE™ Syrup:

Date of most recently revised professional information: 31 October 2018

CLARITYNE™ Tablets:

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)**