PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

CLARITYNE™ 1 mg/ml syrup

Loratadine

Contains sugar: Sucrose 3,0 g

CLARITYNE™ 10 mg tablets

Loratadine

Contains sugar: Lactose monohydrate 0,071 g/tablet

Read all of this leaflet carefully because it contains important information for you.

CLARITYNE™ is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **CLARITYNE™** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **CLARITYNE™** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What **CLARITYNE™** is and what it is used for
2. What you need to know before you take **CLARITYNE™**
3. How to take **CLARITYNE™**
4. Possible side effects
5. How to store **CLARITYNE™**
6. Contents of the pack and other information

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1. **What CLARITYNE™ is and what it is used for:**

- **CLARITYNE™** belongs to a class of medicines known as antihistamines.
- **CLARITYNE™** is an anti-allergy medicine. It helps control your allergic reaction and its symptoms.
- **CLARITYNE™** relieves symptoms associated with seasonal allergic rhinitis (e.g. hay fever), such as sneezing, runny or itchy nose and burning or itchy eyes.
- **CLARITYNE™** may also be used to relieve symptoms of chronic urticaria (itching, redness and number and size of hives) and other allergic skin disorders

2. **What you need to know before you take CLARITYNE™:**

Do not take CLARITYNE™:

- If you are hypersensitive (allergic) to loratadine or any other ingredients of **CLARITYNE™.**

Warnings and precautions:

Take special care with **CLARITYNE™**:

- Safety of **CLARITYNE™** in the elderly has not been established.
- If you have liver disease.
- Weight gain has been reported with the use of loratadine, but the frequency is not known.

Laboratory tests

If you are scheduled to have any skin tests for allergies you should not take **CLARITYNE™** for 48 hours before having these tests, because **CLARITYNE™** may affect tests results.

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Children:

Do not give **CLARITYNE™** to children under 2 years of age.

Other medicines and CLARITYNE™:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

- Ketoconazole (an antifungal medicine used to treat certain kinds of fungal or yeast infections), erythromycin (an antibiotic medicine used to treat certain kinds of bacterial infections and often used for people who have an allergy to penicillins.) or cimetidine (a medicine used treat stomach ulcers, acid reflux, or to prevent and treat symptoms of heartburn associated with acid, indigestion and sour stomach) can enhance the plasma concentrations of loratadine.
- Do not take **CLARITYNE™** together with other medicines known to slow or stop liver metabolism, until further studies can be undertaken.
- If you are scheduled to have any skin tests for allergies you should not take **CLARITYNE™** for two days before having these tests, because this medicine may affect test results.

CLARITYNE™ with food and drink:

CLARITYNE™ can be taken with or without a meal.

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Pregnancy and Breastfeeding:

You should not use **CLARITYNE™** if you are pregnant or breastfeeding your baby.

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

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking **CLARITYNE™**.

Driving and using machines:

At the recommended dose, **CLARITYNE™** is not expected to cause you to be drowsy or less alert.

However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Test your response before driving or performing complicated tasks.

You can suffer sedation if you take alcohol or other central nervous system depressant at the same time as taking **CLARITYNE™**.

CLARITYNE™ contains lactose or sucrose:

CLARITYNE™ contains lactose (syrup) or sucrose (tablets), thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking **CLARITYNE™**.

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3. How to take CLARITYNE™:

For oral use.

Do not share **CLARITYNE™** with any other person.

Always take **CLARITYNE™** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.

CLARITYNE™ Syrup:

The usual dose of CLARITYNE™ Syrup is:

Children 2 to 12 years of age*:*

Body Weight equal to or less than 30 kg, take 5 ml (1 medicine measure) once a day.

Body Weight more than 30 kg, take 10 ml (2 medicine measures) once a day.

Adults and Children 12 years of age and over*:*

Take10 ml (2 medicine measures) once a day.

Do not take **CLARITYNE™** Syrup for longer than 14 days.

CLARITYNE™ Tablets:

The usual dose is:

Adults: Take one tablet once daily.

If you suffer from severe liver impairment you should be administered a lower initial dose because you may have 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.

If you have the feeling that **CLARITYNE™** is too strong or too weak, talk to your doctor or

pharmacist.

If you take more CLARITYNE™ than you should:

If you take more **CLARITYNE™** than you were told to, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

You may experience symptoms of sleepiness, irregular or rapid heartbeat and headache if you take more **CLARITYNE™** than you should. In the event of this happening, treatment should be started immediately.

Treatment: Treatment is symptomatic and supportive.

After emergency treatment, you should continue to be medically monitored.

If you forget to take CLARITYNE™:

If you forget to take your dose on time take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose, to make up for forgotten individual doses.

If you stop taking CLARITYNE™:

There should be no symptoms from stopping taking **CLARITYNE™**; if you experience some consult your doctor or pharmacist.

4. Possible side effects:

CLARITYNE™ can have side effects.

Not all side effects reported for **CLARITYNE™** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CLARITYNE™**

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please consult your doctor, pharmacist or other health care professional for advice.

Contact a doctor or pharmacist if you have any reaction to **CLARITYNE™** that continues, is bothersome or that you think is serious.

Table 1: The following side-effects have been reported and the frequencies are unknown	
Immune system disorders	Anaphylaxis (serious life-threatening allergic reaction) including swelling, angioedema (rapid swelling under the deeper skin layer)
Metabolism and nutrition disorders	Increased appetite
Neurological disorders	Headache, somnolence (Sleepiness, the state of feeling drowsy, ready to fall asleep), sedation (drowsiness), nervousness, dizziness, convulsion, difficulty sleeping
Cardiovascular disorders	Palpitations (unpleasant sensation of irregular and/or forceful beating of the heart), tachycardia (period of very rapid and regular heartbeats that begins and ends suddenly)
Gastro-intestinal disorders	Nausea (feeling sick), dry mouth, gastritis (Inflammation (swelling and redness) of the stomach lining), upset stomach
Hepatobiliary disorders	Abnormal liver function (liver problems)
Skin and subcutaneous tissue disorders	Rash, alopecia (hair loss)
General disorders and administrative site conditions	Fatigue (tiredness)

For serious life-threatening allergic reaction, you may need urgent medical attention or hospitalisation.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to

SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or you can report the side effects directly to Bayer Pharmacovigilance Department by sending an email to zapv@bayer.com or via the Bayer website (www.bayer.co.za). By reporting side effects, you can help provide more information on the safety of CLARITYNE™.

5. How to store CLARITYNE™:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not freeze. (Do not store in a bathroom or a refrigerator).
- Protect from moisture
- Do not use this product after the expiry date that appears on the package.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. Contents of the pack and other information:

What CLARITYNE™ contains:

- **CLARITYNE™ Syrup per 5 ml:**

  The active substance is: Loratadine (micronized) 5 mg.

  The other ingredients are: Citric acid monohydrate, glycerol, peach flavour, propylene glycol, purified water and sucrose

  Preservatives: Sodium benzoate 0.1 % m/v.

  Contains sugar: Sucrose. 3.0 g

- **CLARITYNE™ Tablets per tablet:**

  The active substance is: Loratadine (micronized) 10 mg

  The other ingredients are: Lactose monohydrate, magnesium stearate, maize starch and purified water.

  Contains sugar: Lactose monohydrate 0.071 g

What CLARITYNE™ looks like and contents of the pack:

CLARITYNE™ Syrup:

- Clear, colourless to light-yellow syrup, with a characteristic peach odour and flavour, and free from foreign matter.
- **CLARITYNE™** Syrup is available in amber glass bottles containing 100 ml of syrup.

CLARITYNE™ Tablets:

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

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- **CLARITYNE™** Tablets are available in blister packs of 10 and 30 tablets.

Holder of Certificate of Registration:

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This leaflet was revised in:

CLARITYNE™ Syrup:

Date of most recently revised professional information: 31 October 2018

CLARITYNE™ Tablets:

Date of most recently revised professional information: 31 October 2018

Registration number:

CLARITYNE™ Syrup: Z/5.7.1/56

CLARITYNE™ Tablets: U/5.7.1/27

Access to the corresponding professional information

The corresponding professional information can be accessed on the Bayer website:

http://www.bayer.co.za