SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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

PATIENT INFORMATION LEAFLET

Please note that the patient information leaflet is approved by SAHPRA. MCAZ will be notified of any changes to the contents after SAHPRA approval.

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
CLARITYNE™ Syrup, 5 mg Loratadine, (Syrup)
CLARITYNE™ Tablets, 10 mg Loratadine, (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 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™ 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 perennial and/or 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

BEFORE YOU USE CLARITYNE™

Do not use CLARITYNE™:

- If you are hypersensitive (allergic) to loratadine or any other ingredients of **CLARITYNE™,**
- In children under 2 years of age,

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.

Taking CLARITYNE™ with food and drink:

CLARITYNE™ can be taken with or without a meal.

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 machinery:

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™**

Important information about some of the ingredients of CLARITYNE™:

CLARITYNE™contains lactose or sucrose, 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™**.

TAKING OTHER MEDICINES WITH 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.

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:

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Product Name:	CLARITYNE™
Dosage Form and Strength:	Syrup, 5 mg loratadine per 5 ml & Tablets, 10 mg Loratadine

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.

Effects when treatment with CLARITYNE™ is stopped:
There should be no symptoms from stopping taking **CLARITYNE™**; if you experience some consult your doctor or pharmacist.

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™** 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.

STORING AND DISPOSING OF 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).

PRESENTATION OF CLARITYNE™
CLARITYNE™ Syrup: Amber glass bottles containing 100 ml of syrup.
CLARITYNE™ Tablets: Blister packs of 10 and 30 tablets.

IDENTIFICATION OF CLARITYNE™
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 tablets, scored on one side with the trademark above the score, and the number 10 below the score.

REGISTRATION NUMBER
CLARITYNE™ Tablets: U/5.7.1/27
CLARITYNE™ Syrup: Z/5.7.1/56

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

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Product Name:	CLARITYNE™
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CLARITYNE™ Syrup:
Date on the registration certificate: 15 January 1992
Date of most recently revised patient information leaflet: 31 October 2018
CLARITYNE™ Tablets:
Date on the registration certificate: 03 October 1990
Date of the most recently approved patient information leaflet: 31 October 2018

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