PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

CLAREX 5 film coated tablet

5 mg desloratadine

Contains sugar in the form of lactose anhydrous (4,5 mg/tablet).

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

CLAREX 5 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **CLAREX 5** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **CLAREX 5** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What CLAREX 5 is and what it is used for

CLAREX 5 contains desloratadine which is an antihistamine.

CLAREX 5 is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

• **CLAREX 5** tablets are used for the relief of seasonal hay fever with symptoms such as sneezing, runny nose or itchy nose, itchy palate, and itchy, red, burning or watery eyes.

• **CLAREX 5** may also be taken for allergic skin conditions such as rash, itching or hives (urticaria). Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take CLAREX 5

Do not take CLAREX 5:

• If you are hypersensitive (allergic) to desloratadine or any of the ingredients of **CLAREX 5** (see section 6).

• If you have experienced an allergic reaction with any other antihistamine medicines (such as loratadine, ceterizine).

Warnings and precautions

Take special care with **CLAREX 5**:

• If you are pregnant or breastfeeding (see Pregnancy and Breastfeeding and Fertility).

• If you suffer from a liver or kidney disorder, the dosage you should take may need to be adjusted.

• If you are an elderly patient (as there is a higher risk of unwanted side effects).

• If you have medical or familial history of seizures.

• Safety has not been established in children under the age of 12 years.

• If you have one of the following medical conditions:

- Emphysema (a condition of the lungs)

- Prostatic hypertrophy (enlarged prostrate)

- Narrow angle glaucoma (a condition of the eyes)

- Cardiovascular disorder (a heart condition)

- Epilepsy

- Asthma

• You should stop taking **CLAREX 5** at least 48 hours before having skin allergen testing, as **CLAREX 5** may interfere with the results of such testing.

Do not use **CLAREX 5** for more than 4 weeks without consulting your doctor, pharmacist or healthcare provider as the safety and effectiveness of **CLAREX 5** has not been established if treatment continues for more than 4 weeks.

Children and adolescents

Do not give this medicine to children less than 12 years of age.

Other medicines and CLAREX 5

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

Medicines known to influence **CLAREX 5** are:

• certain anti-fungal medicines (such as ketoconazole).

• certain antibiotic medicines (such as erythromycin, clarithromycin or azithromycin).

• cimetidine, used to treat indigestion and stomach ulcers.

• fluoxetine, used to treat depression.

CLAREX 5 with food and drink and alcohol

CLAREX 5 can be taken with or without food. Grapefruit juice has no effect on how **CLAREX 5** works. Use caution when taking **CLAREX 5** with alcohol.

Pregnancy and breastfeeding and fertility

CLAREX 5 should not be used if you are pregnant or breastfeeding your baby (see Take special care with **CLAREX 5**). Small amount of **CLAREX 5** entering breast milk may cause drowsiness or excitement to your baby.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking **CLAREX 5.**

There is no data available on male/female fertility.

Driving and using machines

CLAREX 5 may make you drowsy or impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while using **CLAREX 5**. It is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicine.

CLAREX 5 contains lactose.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **CLAREX 5**.

CLAREX 5 contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take CLAREX 5

Do not share medicines prescribed for you with any other person.

Always take **CLAREX 5** exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose for adults and children older than 12 years is one tablet, once daily with a glass of water, with or without food.

This medicine is for oral use.

Swallow the tablet whole.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **CLAREX 5**.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.
Your doctor will tell you how long your treatment with **CLAREX 5** will last. Do not stop treatment early because your disease may get worse.

If you have the impression that the effect of **CLAREX 5** is too strong or too weak, tell your doctor or pharmacist.

If you take more CLAREX 5 than you should

In event of overdosage, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, that the doctor may know what you have taken.

If you forget to take CLAREX 5

If you forget to take a dose, take it as soon as you remember.

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

4. Possible side effects

CLAREX 5 can have side effects.

Not all side effects reported for **CLAREX 5** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **CLAREX 5**, please consult your health care provider for advice.

If any of the following happens, stop taking **CLAREX 5** and tell your doctor immediately or go to the casualty department at your nearest hospital:

• swelling of hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

• rash or itching.

• abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite).

These are all very serious side effects. If you have them, you may have a serious allergic reaction to **CLAREX 5**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• you bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia).

• hallucinations (seeing things that aren't there).

• convulsions (fits).

• fast, pounding or irregular heartbeat or pulse (tachycardia).

• low blood pressure (hypotension).

• fatigue

• hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain).

• yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

• abnormal blood test results including anaemia.

• increased appetite and weight gain

• feeling depressed, abnormal behaviour, aggressive, sleep disturbances, nightmares, confusion, restlessness.

• dizziness, drowsiness, headache, nervousness, shaking, tingling or numbness in the hands or feet.

• blurred vision.

• ringing in the ears.

• pharyngitis (body aches or pain, congestion, cough, hoarseness, runny nose).

• shortness of breath, tightness in chest and wheezing.

• nausea, vomiting, acid or sour stomach, stomach pain or discomfort, diarrhoea, dry mouth.

• redness of the skin, hives or welts, skin rash, sensitivity to light, severe itching, hair loss, sweating.

• muscle pain or muscle cramps.

• difficult or painful menstruation.

• unusual tiredness, weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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. Reporting can also be done directly to Unicorn Pharmaceuticals at: vigilance@unicornpharma.co.za. By reporting side effects, you can help

provide more information on the safety of **CLAREX 5.**

5. How to store CLAREX 5

• Store at or below 25 °C in a well closed container.

• Protect from light.

• Do not remove from the outer carton until required for use.

• STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

• Return all unused medicine to your pharmacist.

• Do not use the tablets after the expiry date printed on the blisters and containers.

• Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLAREX 5 contains

Each film coated tablet contains 5 mg desloratadine.

The other ingredients are hypromellose, lactose anhydrous, magnesium oxide, microcrystalline cellulose, Opadry blue, pregelatinised starch, purified water and zinc stearate.

CLAREX 5 contains sugar in the form of lactose anhydrous.

What CLAREX 5 looks like and contents of the pack

CLAREX 5 is a blue, round, film-coated tablet debossed with a "D" on one side of the tablet and plain on the other.

Blister strips:

CLAREX 5 is packed into hard, silver-coloured aluminium foil / transparent PVC / PCTFE film blister strips of 1 X 7 tablets, 1 x 10 tablets or 3 x 10 tablets each inside an outer cardboard box.

HDPE bottles:

CLAREX 5 is also packed into white, HDPE bottles with a desiccant and white HDPE screw cap with 30 tablets inside.

Holder of Certificate of Registration

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