PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

NAME OF THE MEDICINE

Clarex ODT 2,5 / 5 orodispersible tablets

Desloratadine

Clarex ODT 2,5 contains:

Sugar: mannitol (66,7 mg/tablet).

Sweetener: aspartame (1,5 mg/tablet).

Clarex ODT 5 contains:

Sugar: mannitol (133,5 mg/tablet).

Sweetener: aspartame (3 mg/tablet).

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **Clarex ODT** 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.

What is in this leaflet

1. What **Clarex ODT** is and what it is used for
2. What you need to know before you take **Clarex ODT**
3. How to take **Clarex ODT**
4. Possible side effects

5. How to store **Clarex ODT**

6. Contents of the pack and other information

1. What Clarex ODT is and what it is used for

Clarex ODT tablets contain the active ingredient desloratadine.

Clarex ODT is used for the relief of seasonal hay fever and for the relief of symptoms associated with hives (a skin condition).

2. What you need to know before you take Clarex ODT

Do not take Clarex ODT:

- If you are hypersensitive (allergic) to desloratadine or any of the other ingredients of **Clarex ODT** (listed in section 6)

Warnings and precautions:

Tell your doctor or health care provider before being given Clarex ODT:

Special care should be taken with Clarex ODT:

- if you have poor kidney function,
- if you have medical or familial history of seizures.

Safety has not been established in children younger than 6 years of age.

Do not take **Clarex ODT** for a period exceeding 4 weeks.

Other medicines and Clarex ODT:

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

Please consult your health care provider for advice if you are taking the following medicines:

- Azithromycin
- Norfloxetine

- Fluoxetine

Clarex ODT with food, drink and alcohol:

Clarex ODT may be taken with or without food. **Clarex ODT** can be taken with water.

Use caution when taking **Clarex ODT** with alcohol.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, 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 ODT**.

Do not take **Clarex ODT** if you are breastfeeding your baby. Please consult your doctor, pharmacist, or other health care provider for advice.

Driving and using machines:

Clarex ODT may impair your ability to drive and use machinery. Do not drive a vehicle, operate machinery, or do anything else that could be dangerous until you know how you will react to **Clarex ODT.**

Important information about some of the ingredients of Clarex ODT

Aspartame (sweetener)

Clarex ODT 2,5

This medicine contains 1,5 mg aspartame (sweetener) in each tablet.

Clarex ODT 5

This medicine contains 3 mg aspartame (sweetener) in each tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Mannitol (sugar)

Clarex ODT 2,5

This medicine contains 66,7 mg mannitol (sugar) in each tablet.

Clarex ODT 5

This medicine contains 133,5 mg mannitol (sugar) in each tablet.

3. How to take Clarex ODT

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

Always take **Clarex ODT** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **Clarex ODT** is for oral use only.

The usual dose for the **paediatric population (6 to 11 years)** is:

One **Clarex ODT 2,5** orodispersible tablet placed in the mouth once a day.

The usual dose for **adolescents and adults (≥ 12 years)** is:

One **Clarex ODT 5** orodispersible tablet placed in the mouth once a day.

Immediately before use, the blister must be carefully peeled open and the dose of orodispersible tablet removed without crushing it. The dose of orodispersible tablet is placed in the mouth where it will disperse immediately. Water or other liquid is not needed to swallow the dose. The dose must be taken as soon as the blister has been opened.

Do not take **Clarex ODT** for a period exceeding 4 weeks (see **Take special care with Clarex ODT**).

Clarex ODT can be taken with or without food, regardless of mealtime.

If you take more Clarex ODT than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Always take the labelled medicine package with you, whether there are any **Clarex ODT** tablets left or not.

If you forget to take Clarex ODT:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take **Clarex ODT** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Clarex ODT can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Clarex ODT** 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:

Side effects with an unknown frequency:

- Changes in the way your heart beats, for example, if you notice it beating faster and/or pauses
- Liver failure, liver damage and yellowing of your skin and eyes (jaundice), inflammation of your liver

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Headache
- Dry mouth, unusual tiredness or weakness
- Muscle pain.

Side effects with an unknown frequency:

- Dizziness
- Drowsiness
- Difficulty falling asleep or staying asleep
- Stomach pain, nausea, vomiting, diarrhoea, indigestion, heartburn.

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, pharmacist or nurse. You can also report side effects via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more

information on the safety of Clarex ODT.

By reporting side effects, you can help provide more information on the safety of **Clarex ODT**.

5. How to store Clarex ODT

- Store below 30 °C.
- Protect from moisture.
- Keep blisters in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Clarex ODT contains:

The active ingredient is desloratadine.

The other ingredients are:

Aspartame

Citric acid monohydrate

Croscarmellose sodium

Iron oxide red E172

Magnesium stearate

Mannitol

Microcrystalline cellulose

Polacrilin potassium

Potassium hydroxide (for pH-adjustment)

Purified water

Tutti-frutti flavour

Tutti-frutti flavour contains:

Flavouring

Modified starch E1450

Maltodextrin

Propylene glycol E1520

What Clarex ODT looks like and contents of the pack:

Clarex ODT 2,5: Red-brick, round, flat tablets with bevelled edges and '2.5' embossed on one side.

Clarex ODT 5: Red-brick, round, flat tablets with bevelled edges and '5' embossed on one side.

Clarex ODT is packed in Aluminium / peelable Aluminium blisters. The blisters are then packed into cartons.

Pack sizes

Clarex ODT 2,5 pack sizes: 10, 30, 50, 60, 90, 100 and 150

Clarex ODT 5 pack sizes: 10, 20, 30, 50, 60, 90 and 100

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Unicorn Pharmaceuticals (Pty) Ltd

Cnr. Searle & Pontac Streets,

Cape Town,

South Africa, 8001

This leaflet was last revised in:

To be allocated by SAHPRA upon registration.

Registration numbers:

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