Patient Information Leaflet for CLAREX ORAL SOLUTION PATIENT

INFORMATION LEAFLET

SCHEDULING STATUS

S2

CLAREX ORAL SOLUTION 2,5 mg per 5 mL oral solution

Desloratadine

Contains artificial sweetener: 2 mg/mL sucralose.

Contains sugar alcohol: 150 mg/mL sorbitol.

Contains sweetener: Sucralose (2 mg/mL).

Solvent: Propylene glycol (E1520) (150 mg/mL).

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

CLAREX ORAL SOLUTION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you or your child still need to take CLAREX ORAL SOLUTION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CLAREX ORAL SOLUTION 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 a few days.

What is in this leaflet

1. What CLAREX ORAL SOLUTION is and what it is used for
2. What you need to know before you or your child take CLAREX ORAL SOLUTION
3. How to take CLAREX ORAL SOLUTION
4. Possible side effects
5. How to store CLAREX ORAL SOLUTION

6. Contents of the pack and other information.

1. What CLAREX ORAL SOLUTION is and what it is used for

CLAREX ORAL SOLUTION contains desloratadine which is an antihistamine.

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

CLAREX ORAL SOLUTION relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults, adolescents and children 2 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate and itchy, red or watery eyes.

CLAREX ORAL SOLUTION is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

2. What you need to know before you or your child take CLAREX ORAL SOLUTION

Do not take CLAREX ORAL SOLUTION:

- If you or your child is hypersensitive (allergic) to desloratadine or any of the inactive ingredients of CLAREX ORAL SOLUTION (see section 6).

Warnings and precautions

Take special care with CLAREX ORAL SOLUTION if you or your child:

- Have poor kidney function.
- Have medical or familial history of seizures (epilepsy).

Children and adolescents

Do not give CLAREX ORAL SOLUTION to children less than 2 years of age.

Other medicines and CLAREX ORAL SOLUTION:

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

There are no known interactions of CLAREX ORAL SOLUTION with other medicines.

Tell your doctor or pharmacist if you or your child is taking, have recently taken or might take any other medicines.

CLAREX ORAL SOLUTION with food, drink and alcohol:

CLAREX ORAL SOLUTION may be taken with or without a meal.

Use CLAREX ORAL SOLUTION with caution when taking 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 ORAL SOLUTION.

Do not take CLAREX ORAL SOLUTION if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

Driving and using machines:

At the recommended dose, CLAREX ORAL SOLUTION is not expected to affect your ability to drive a vehicle or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a vehicle or operating machinery until you have established your own response to CLAREX ORAL SOLUTION.

CLAREX ORAL SOLUTION contains sorbitol:

CLAREX ORAL SOLUTION contains sorbitol. If you have been told by your doctor that you or your child has an intolerance to some sugars, contact your doctor before taking CLAREX ORAL SOLUTION.

3. How to take CLAREX ORAL SOLUTION

Always take CLAREX ORAL SOLUTION exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

CLAREX ORAL SOLUTION is for oral use only.

Children 2 to 5 years of age:

Take 2,5 mL (½ of a 5 mL spoonful) CLAREX ORAL SOLUTION once a day, with or without a meal.

Children 6 to 11 years of age:

Take 5 mL (one 5 mL spoonful) CLAREX ORAL SOLUTION once a day, with or without a meal.

Adults and adolescents 12 years of age and older:

Take 10 mL (two 5 mL spoonfuls) CLAREX ORAL SOLUTION once a day, with or without a meal.

If you or your child take more CLAREX ORAL SOLUTION than instructed:

In event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining solution with you, so that the doctor knows what you or your child have taken.

If you or your child missed a dose of CLAREX ORAL SOLUTION:

If you or your child forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dosage at the usual time.

4. Possible side effects

CLAREX ORAL SOLUTION can have side effects.

Not all side effects reported for CLAREX ORAL SOLUTION are included in this leaflet. Should your or your child's general health worsen, or if you or your child experience any untoward effects while taking CLAREX ORAL SOLUTION, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking CLAREX ORAL SOLUTION 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 or your child have them, you or your child may have had a serious reaction to CLAREX ORAL SOLUTION. You or your child 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:

Less frequent:

- Seizures (fits).
- Fast, irregular heartbeats.

Frequency unknown:

- Hepatitis (also called jaundice, characterised by yellowing of the skin and eyes).

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Headache.

Less frequent:

- Hallucinations (seeing or hearing things that do not exist).
- Dizziness, sleepiness, sleeping problems, a feeling of restlessness (associated with a movement increase in the larger parts of the body).
- Stomach pain, nausea (feeling sick), vomiting (being sick), heartburn, diarrhoea, dry mouth.
- Abnormal liver function test results.
- Myalgia (muscle pain).
- Unusual weakness or tiredness.
- Fever.

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

Reporting of side effects:

If you or your child 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. By reporting side effects, you can help provide more information on the safety of CLAREX ORAL SOLUTION.

5. How to store CLAREX ORAL SOLUTION

Store at or below 30 °C.

Keep blister strips in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated 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 ORAL SOLUTION contains:

The active substance is desloratadine.

The inactive ingredients are: hypromellose, sucralose, citric acid, sodium citrate, sorbitol, propylene glycol, tutti frutti flavourant (propylene glycol, flavouring substances), purified water.

What CLAREX ORAL SOLUTION looks like and contents of the pack:

CLAREX ORAL SOLUTION is a clear, colourless solution with a pleasant fruity odour.

CLAREX ORAL SOLUTION is filled into amber type III glass bottles of 30 / 60 / 100 / 125 / 150 / 220/ 250 / 300 mL and closed with a white plastic child-resistant screw cap.

Holder of Certificate of Registration:

Unicorn Pharmaceuticals (Pty) Ltd

Cnr. Searle & Pontac Streets

Cape Town

8001

South Africa

This leaflet was last revised in

To be allocated by SAHPRA upon registration.

Registration number

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