PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DERALIQE 5 mg film-coated tablets

Desloratadine

Contains sugar: Anhydrous lactose (20 mg per tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DERALIQE with any other person.
- Ask your healthcare provider or 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 DERALIQE is and what it is used for.

2. What you need to know before you take DERALIQE.

3. How to take DERALIQE.

4. Possible side effects.

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1. What DERALIQE is and what it is used for

DERALIQE contains desloratadine which is an antihistamine. DERALIQE is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

DERALIQE 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 and adolescents 12 years of age and older. These symptoms include sneezing, runny or itching nose, itchy palate, and itchy, red or watery eyes.

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

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 DERALIQE

Do not take DERALIQE:

- If you are hypersensitive (allergic) to desloratadine or any of the other ingredients of DERALIQE (listed in section 6) or to loratadine.

Warnings and precautions

Take special care with DERALIQE:

- If you have poor kidney function.
- If you have medical or familial history of seizures.
- Do not use DERALIQE for longer than 4 weeks without speaking to your doctor.

Children and adolescents

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

Other medicines and DERALIQE

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

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

- Azithromycin (an antibiotic)
- Norfluoxetine or fluoxetine (an antidepressant).

DERALIQE with food, drink and alcohol

Use with caution when taking DERALIQE with alcohol.

Pregnancy, breastfeeding, and fertility

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 healthcare provider for advice before taking DERALIQE.

Taking DERALIQE is not recommended if you are pregnant or breastfeeding a baby.

Driving and using machines

DERALIQE does not usually cause drowsiness. However, in a small number of patients, drowsiness may be experienced.

It is not always possible to predict to what extent DERALIQE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DERALIQE affects you.

DERALIQE contains anhydrous lactose.

DERALIQE contains anhydrous lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DERALIQE.

3. How to take DERALIQE

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

Always take DERALIQE exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose of DERALIQE for adults and adolescents 12 years of age and older is one tablet once a day with water, with or without food. This medicine is for oral use and the tablet should be swallowed whole.

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take DERALIQE.
If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend 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 doctor may recommend 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 doctor.

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

If you take more DERALIQE than you should

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

If you forget to take DERALIQE

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

4. Possible side effects

DERALIQE can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- shortness of breath;
- rash or itching;
- hives;
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache;
- dry mouth;
- fatigue.

Less frequent side effects:

- pounding or irregular heartbeat;
- fast heartbeat;
- seizures;
- restlessness with increased body movement;

- hallucinations;
- abdominal pain, tiredness, nausea, vomiting, yellowing of the skin and the whites of the eyes – these may indicate a problem with your liver;
- stomach ache;
- feeling sick (nausea);
- vomiting;
- upset stomach (indigestion);
- diarrhoea;
- dizziness;
- drowsiness;
- inability to sleep;
- muscle pain.

The following side effects have been reported but the frequency is unknown:

- feeling down (depressed);
- dry eyes;
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium;
- unusual weakness;
- abnormal behaviour;
- aggression;
- weight increased;
- increased appetite.

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 “Adverse Drug Reaction and Quality Problem Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

In addition, side effects can also be reported to info@pharmacorp.co.za.

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

5. How to store DERALIQE

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Store in the original package / container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the blister/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DERALIQE contains:

- The active substance is desloratadine.

  Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients are:

  Tablet core: Anhydrous lactose, calcium hydrogen phosphate anhydrous, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous.

  Tablet coating: Hypromellose, indigo carmine lake (E-132), macrogol 6000, talc, titanium dioxide (E-171).

What DERALIQE looks like and contents of the pack

Round, biconvex, blue film-coated tablets debossed with a “D” on one side.

Contents of the pack:

DERALIQE film-coated tablets are packed in aluminium/polyamide-aluminium-PVC blister strips in a cardboard box. Pack size of 10 and 30 film-coated tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.