

PATIENT INFORMATION LEAFLET**Scheduling status**

S2

DESEBLOK 0.5 mg/ml Oral solution

Desloratadine

Contains artificial sweetener: Sucralose 2 mg/ml

Contains sugar alcohol: Sorbitol 150 mg/ml

Contains propylene glycol 750 mg/5 ml

Read all of this leaflet carefully before you start taking DESEBLOK 0.5 mg/ml

DESEBLOK 0.5 mg/ml is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you or your child still need to take DESEBLOK 0.5 mg/ml carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DESEBLOK 0.5 mg/ml 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 DESEBLOK 0.5 mg/ml is and what it is used for
2. What you need to know before you or your child take DESEBLOK 0.5 mg/ml
3. How to take DESEBLOK 0.5 mg/ml
4. Possible side effects
5. How to store DESEBLOK 0.5 mg/ml
6. Contents of the pack and other information

1. What DESEBLOK 0.5 mg/ml is and what it is used for

DESEBLOK 0.5 mg/ml contains desloratadine which is an antihistamine.

DESEBLOK 0.5 mg/ml is an anti-allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

DESEBLOK 0.5 mg/ml 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.

DESEBLOK 0.5 mg/ml 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 DESEBLOK 0.5 mg/ml

Do not take DESEBLOK 0.5 mg/ml

- if you or your child is hypersensitive (allergic) to desloratadine or any of the inactive ingredients of DESEBLOK 0.5 mg/ml (see section 6).

Warnings and precautions

Take special care with DESEBLOK 0.5 mg/ml if you or your child

- have poor kidney function.
- have a medical or family history of seizures (epilepsy).

Children and adolescents

Do not give DESEBLOK 0.5 mg/ml to children less than 2 years of age.

Other medicines and DESEBLOK 0.5 mg/ml

Always tell your healthcare provider if you or your child is taking any other medicine (this includes complementary or traditional medicines).

There are no known interactions of DESEBLOK 0.5 mg/ml with other medicines.

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

DESEBLOK 0.5 mg/ml with food, drink and alcohol

DESEBLOK 0.5 mg/ml may be taken with or without a meal.

Use DESEBLOK 0.5 mg/ml 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 healthcare provider for advice before taking DESEBLOK 0.5 mg/ml.

Do not take DESEBLOK 0.5 mg/ml 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, DESEBLOK 0.5 mg/ml 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 DESEBLOK 0.5 mg/ml.

DESEBLOK 0.5 mg/ml contains sorbitol

DESEBLOK 0.5 mg/ml 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 DESEBLOK 0.5 mg/ml.

DESEBLOK 0.5 mg/ml contains propylene glycol

DESEBLOK 0.5 mg/ml contains 750 mg propylene glycol per 5 ml. Talk to your doctor or pharmacist before taking DESEBLOK 0.5 mg/ml, when other medicines that you take contain propylene glycol or alcohol.

3. How to take DESEBLOK 0.5 mg/ml

Always take DESEBLOK 0.5 mg/ml exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DESEBLOK 0.5 mg/ml is for oral use only.

Children 2 to 5 years of age:

Take 2,5 ml ($\frac{1}{2}$ of a 5 ml spoonful) DESEBLOK 0.5 mg/ml once a day, with or without a meal.

Children 6 to 11 years of age:

Take 5 ml (one 5 ml spoonful) DESEBLOK 0.5 mg/ml once a day, with or without a meal.

Adults and adolescents (12 years of age and older):

Take 10 ml (two 5 ml spoonfuls) DESEBLOK 0.5 mg/ml once a day, with or without a meal..

If you or your child take more DESEBLOK 0.5 mg/ml than instructed

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control 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 DESEBLOK 0.5 mg/ml

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 forgotten individual doses. Continue to take the next dosage at the usual time.

4. Possible side effects

DESEBLOK 0.5 mg/ml can have side effects.

Not all side effects reported for DESEBLOK 0.5 mg/ml are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while taking DESEBLOK 0.5 mg/ml, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking DESEBLOK 0.5 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of 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 DESEBLOK 0.5 mg/ml. 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
- 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 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 to SAHPRA via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DESEBLOK 0.5 mg/ml.

5. How to store DESEBLOK 0.5 mg/ml

Store all medicines out of reach of children.

Store at or below 30 °C, in the original package.

Do not use DESEBLOK 0.5 mg/ml after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 DESEBLOK 0.5 mg/ml contains

The active substance is desloratadine.

Each 5 ml of contains 2,5 mg desloratadine.

The other ingredients are: Hypromellose, sucralose, citric acid, sodium citrate, sorbitol, propylene glycol, Tutti Frutti flavour and purified water.

What DESEBLOK 0.5 mg/ml looks like and contents of the pack

DESEBLOK 0.5 mg/ml is a clear, colourless solution.

DESEBLOK 0.5 mg/ml is supplied in amber glass bottles of 60 ml and 100 ml closed with a white plastic child resistant screw cap. The bottle is packed into an outer carton. Not all packs may be marketed at any one time.

Holder of certificate of registration

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7570

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