

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

DEHRIN® SOLUTION

Desloratadine 2,5 mg/5 ml

Contains sugar: Sorbitol 147,15 mg/ml

Contains artificial sweetener: Sucralose 1 mg/ml

Contains propylene glycol: 102,3 mg/ml

Contains sodium: 4,4 mg/ml

Read all of this leaflet carefully because it contains important information for you and/or your child

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

- Keep this leaflet. You may need to read it again.
- Do not share DEHRIN SOLUTION 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, or your child's, symptoms worsen or do not improve.

What is in this leaflet

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

6. Contents of the pack and other information

1 What DEHRIN SOLUTION is and what it is used for

DEHRIN SOLUTION is an antihistamine that reduces the natural chemical histamine in the body. Histamine can produce symptoms of sneezing, itching, watery eyes, and runny nose. DEHRIN SOLUTION is used to treat these symptoms of allergies.

2 What you need to know before you or your child take DEHRIN SOLUTION

Do not take DEHRIN SOLUTION, or give it to your child, if she/he/you are:

- allergic to desloratadine, loratadine, other antihistamines, or any of the ingredients of DEHRIN SOLUTION (see section 6 “What DEHRIN contains”);
- pregnant, trying to become pregnant or breastfeeding.

Do not use DEHRIN SOLUTION in children under the age of two years, as safety and efficacy have not been established in children in this age group.

Warnings and precautions

Take special care with DEHRIN SOLUTION:

The presence of other medical problems may affect the use of DEHRIN SOLUTION. Talk to your doctor, pharmacist or health care provider before you or your child take DEHRIN SOLUTION, if he/she/you:

- have a kidney or liver problem;
- are an elderly patient;
- have epilepsy (seizures or convulsions).

DEHRIN SOLUTION may increase appetite and lead to weight gain (see POSSIBLE SIDE EFFECTS.) You should monitor your child’s weight and talk to your doctor if the weight gain becomes marked.

You should stop taking DEHRIN SOLUTION 48 hours before having skin tests using allergen extracts.

Safety and efficacy of DEHRIN SOLUTION for treatment periods in excess of 4 weeks for allergic rhinitis (runny nose) are unknown.

Children

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

Other medicines and DEHRIN SOLUTION

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

Make sure that your doctor knows that you (or your child) are also taking the following medicines:

- Ketoconazole (an antifungal medicine, used for infections such as dandruff, jock itch, athlete's foot);
- Erythromycin, azithromycin (antibiotic medicines, used for various infections);
- Fluoxetine (a medicine used for depression);
- Cimetidine (a medicine used for heartburn and ulcers in your stomach or gut).

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, pharmacist or healthcare professional.

DEHRIN SOLUTION with food, drink and alcohol

You or your child can take DEHRIN SOLUTION with or without food.

Use DEHRIN SOLUTION with caution when taking with alcohol.

Pregnancy, breastfeeding and fertility

DEHRIN SOLUTION should not be used if you are pregnant, trying to become pregnant or 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 DEHRIN SOLUTION.

There is no data on male/female fertility.

Driving and using machines

At the recommended dose, DEHRIN SOLUTION is not expected to cause you to be drowsy or less alert. However, some people may experience drowsiness and dizziness, which may affect their ability to drive or use machines. Do not drive or operate tools or machines if you do get drowsy or dizzy with DEHRIN SOLUTION.

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

DEHRIN SOLUTION contains sucralose

DEHRIN SOLUTION contains 1 mg sucralose (an artificial sweetener) per ml oral solution.

DEHRIN SOLUTION contains sorbitol

DEHRIN SOLUTION contains 147,15 mg sorbitol in each ml of oral solution. Sorbitol is a source of fructose.

If you have been told that you (or your child) have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, you (or your child) should not take DEHRIN SOLUTION.

DEHRIN SOLUTION contains propylene glycol

DEHRIN SOLUTION contains 102,30 mg propylene glycol in each ml of oral solution.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them DEHRIN SOLUTION, in particular if they use other medicines that contain propylene glycol or alcohol.

DEHRIN SOLUTION contains sodium

DEHRIN SOLUTION contains 4,4 mg sodium per 1 ml oral solution. This is less than 1 mmol sodium per ml oral solution, that is to say essentially 'sodium-free'. Please tell your doctor or nurse if you are on a low sodium diet.

3 How to take or give DEHRIN SOLUTION

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

Always take DEHRIN SOLUTION, or give it to your child, exactly as your doctor, your child's doctor or pharmacist has told you. Check with your doctor or your child's doctor or your pharmacist if you are unsure.

Your or your child's doctor will tell you how long your/his/her treatment with DEHRIN SOLUTION will last.

Safety and efficacy have not been confirmed for more than 4 weeks of treatment.

If you have the impression that DEHRIN SOLUTION is too strong or too weak, you should talk to your or your child's doctor or pharmacist.

Children 2 to 5 years old

2,5 ml (half of a 5 ml medicine spoonful) once daily with or without food.

Children 6 to 11 years old

5 ml (one 5 ml medicine spoonful) once daily with or without food.

Adults and children 12 years of age and older

10 ml (two 5 ml medicine spoonfuls) once daily with or without food.

If an oral measuring syringe is provided with the bottle of DEHRIN SOLUTION, you can use it to take or give the appropriate amount of oral solution.

If you take more DEHRIN SOLUTION than you should, or if you give your child more DEHRIN SOLUTION than you should

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

Overdose symptoms may include fast heart rate and sleepiness. You may experience an increase in side effects and their frequency.

If you forget to take DEHRIN SOLUTION, or if you forget to give it to your child

If you or your child miss a dose of DEHRIN SOLUTION, take or give it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule.

Do not take a double dose or give a double dose to your child to make up for forgotten individual doses.

If you stop taking DEHRIN SOLUTION

Should you wish to stop treatment early, ask your doctor, pharmacist or nurse for advice.

4 Possible side effects

DEHRIN SOLUTION can have side effects.

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

If any of the following happens to you or your child, stop taking DEHRIN SOLUTION, or stop giving it to your child. Tell your doctor/your child's doctor immediately, or go to the casualty department at your nearest hospital:

Severe allergic reactions (anaphylaxis, angioedema):

- Hives; itchy rash, difficulty breathing; swelling of your/his/her face, lips, tongue, or throat, trouble swallowing or breathing (dyspnoea).

These are all very serious side effects. If you or your child have them, you may have had a serious reaction to DEHRIN 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:

- A fast, pounding, or uneven heartbeat, or a slow heartbeat;
- Yellow eyes and skin, nausea and abdominal pain (these could be signs of jaundice or hepatitis).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache
- Fatigue (tiredness)
- Dry mouth

- Sore throat

Frequent side effects in children:

- Diarrhoea
- Fever
- Insomnia (sleeping problems)

Less frequent side effects

- Muscle pain, joint pain, swollen joints, muscle aching, cramping or stiffness, difficulty in moving
- Drowsiness, sleepiness, sleeplessness
- Nausea, diarrhoea, stomach pain, vomiting, heartburn
- Dizziness, blurred vision
- Low blood pressure
- Urticaria (hives or welts, itching, redness of skin, skin rash)
- Painful menstruation
- Hallucinations (seeing and hearing things that do not exist)
- Hyperactivity, seizures ("fits")

Unknown frequency

- Asthenia (abnormal physical weakness or lack of energy)
- Swelling
- Sweating
- 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
- Changes in the way the heart beats

- Shortness of breath and/or a tightness in the chest
- Abnormal behaviour
- Aggression
- Increased appetite, weight increased (see “Take special care with DEHRIN SOLUTION”)

Unknown frequency in Children

- Slow heartbeat
- Change in the way the heart beats
- Abnormal behaviour
- Aggression

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of DEHRIN SOLUTION.

5 How to store DEHRIN SOLUTION

Store all medicines out of reach of children.

Store in the original packaging at or below 25 °C. Keep bottle in carton until required for use.

Keep the bottle tightly closed.

Use within 4 months from first opening.

Do not store your medicine in the bathroom.

Do not use DEHRIN SOLUTION after the expiry date printed on the label or carton.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What DEHRIN SOLUTION contains

- The active substance is desloratadine.

Each 5 ml of DEHRIN SOLUTION contains 2,5 mg desloratadine.

- The other ingredients are:

Citric acid monohydrate, disodium edetate, hypromellose 2910, propylene glycol (10,23 %), purified water, sodium citrate, sorbitol, sucralose and Tutti Frutti flavouring.

What DEHRIN SOLUTION looks like and contents of the pack

DEHRIN SOLUTION is a clear colourless solution, free from foreign matter.

DEHRIN SOLUTION is supplied in amber glass bottles closed with a white round plastic child resistant (C/R) screw closure consisting of an outer and an inner layer of polypropylene and polyethylene respectively in six different volume sizes, i.e. 50, 60, 100, 120, 150 and 300 ml. The bottles are subsequently packed into cardboard boxes. All packages are supplied with an oral measuring syringe with a final volume of 5 ml marked on every 0,5 ml.

Not all pack sizes may necessarily be marketed at any one time.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

For Professional Information (PI), please refer to <https://medsinfo.sahpra.org.za/home>.