PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DAZIT® SYRUP

(Desloratadine 2,5 mg/5 mL)

(Contains sucralose 10 mg/5 mL, sorbitol 750 mg/5 mL and sodium 6,3 mg/5 mL)

Read all of this leaflet carefully before you start taking DAZIT® SYRUP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **DAZIT® SYRUP** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DAZIT® SYRUP is and what it is used for

What DAZIT® SYRUP is

DAZIT® SYRUP contains desloratadine which is an antihistamine.

How DAZIT® SYRUP works

DAZIT® SYRUP is an antiallergy medicine that does not make you drowsy. It helps control

your allergic reaction and its symptoms.

When DAZIT® SYRUP should be used

DAZIT® SYRUP 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 year of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

DAZIT® SYRUP 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 DAZIT® SYRUP

Do not take DAZIT® SYRUP:

If you are allergic to desloratadine, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Take special care with DAZIT® SYRUP:

- if you have poor kidney function
- if you have medical or familial history of fits (seizures)
- if you have fructose/glucose/sucrose intorelance

Safety of this medicine has not been reported beyond 4 to 6 weeks. Do check with your doctor if you have to take this medicine for longer duration.

Children and adolescents

Do not give this medicine to children less than 2 years of age.

Other medicines and DAZIT® SYRUP

Always tell your healthcare professional if you are taking any other medicine.

(This Includes complementary or traditional medicine).

There are no known interactions of **DAZIT® SYRUP** with other medicines.

DAZIT® SYRUP with food

DAZIT® SYRUP may be taken with or without food.

DAZIT® SYRUP with alcohol

Use caution when taking DAZIT® SYRUP with alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking DAZIT® SYRUP is not recommended if you are pregnant or nursing a baby.

There is no data reported on male/female fertility.

Driving and using machines

At the recommended dose, this medicine is not expected to affect your ability to drive 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 car or operating machinery until you have established your own response to the medicine.

DAZIT® SYRUP contains sucrose and sorbitol

This medicine contains 150 mg sorbitol in each mL of oral solution.

Sorbitol is a source of fructose. If your doctor has told you 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, talk to your doctor before you (or your child) take or receive this medicine.

DAZIT® SYRUP contains propylene glycol (E1520)

This medicine contains 150 mg propylene glycol (E1520) in each mL of oral solution.

DAZIT® SYRUP contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take DAZIT® SYRUP

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in children

Children 2 to 5 years of age:

The recommended dose is 2,5 mL (½ of a 5 mL spoonful) of oral solution once a day.

Children 6 to 11 years of age:

The recommended dose is 5 mL (one 5 mL spoonful) of oral solution once a day.

Use in adults and adolescents 12 years of age and over

The recommended dose is 10 mL (two 5 mL spoonful) of oral solution once a day.

In case an oral measuring syringe is provided with the medicine, you can alternatively use it to take the appropriate amount of the medicine dose.

Method of administration

This medicine is for oral use.

You can take this medicine with or without food.

If you take more DAZIT® SYRUP than you should

Take DAZIT® SYRUP only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more DAZIT® SYRUP than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take DAZIT® SYRUP

If you forget to take your 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 a forgotten dose.

If you stop taking DAZIT® SYRUP

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in most children and adults, side effects reported with desloratadine were about the same as reported with a dummy solution or tablet. However, common side effects

reported in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

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

Severe allergic reactions (anaphylaxis, angioedema): Swelling of the face, mouth, tongue, throat, hands, or feet, and/or a raised itchy rash (hives), trouble swallowing or breathing (dyspnoea).

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to DAZIT® SYRUP. 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:

- Irregular heart beat (QT prolongation)
- Liver inflammation (Hepatitis): The symptoms of hepatitis are nausea (feeling sick) or vomiting (being sick), loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- Fits (seizures)

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

Other side-effects:

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache

- Difficulty in sleeping (Insomnia); *Frequent in children less than 2 years*
- Dry mouth
- Loose stool (diarrhoea); *Frequent in children less than 2 years*
- Tiredness (fatigue)
- Fever (frequent in children less than 2 years)

Less frequent side effects:

- Seeing or hearing things that are not there (Hallucinations)
- Dizziness,
- Sleepiness (somnolence)
- Difficulty in sleeping (insomnia)
- Excessive mobility and impulsivity preventing normal functioning (psychomotor hyperactivity)
- Fast heart beats (tachycardia)
- Palpitations
- Abdominal (belly) pain,
- Feeling unwell (nausea)
- Vomiting
- Indigestion (dyspepsia)
- Loose motions (diarrhea)
- Abnormal liver function tests
- Muscle pain (myalgia)
- Itching (pruritus)
- Rash
- Hives (urticaria)

Side effects with frequency unkown:

- Increased appetite
- Abnormal behaviour, aggression
- Yellowing of the skin and/or eyes (jaundice)
- 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 (photosensitivity)
- Unusual weakness (asthenia)
- Weight increased

If you notice any other 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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc. org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DAZIT® SRYUP.

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration (HCR) via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5. How to store DAZIT® SYRUP

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30 °C. Protect from light

- Keep container tightly closed.
- Store in the original container
- Keep the container in the outer carton.
- Do not use after the expiry date stated on the label / 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 DAZIT® SYRUP contains

The active substance is desloratadine.

The other ingredients are: Hypromellose, sucralose, citric acid, sodium citrate, liquid (non-crystallising) sorbitol, propylene glycol, liquid tutti frutti flavour, purified water.

What DAZIT® SYRUP looks like and contents of the pack

DAZIT® SYRUP is a clear colourless solution. Is it packed in amber glass type III bottles of 100 mL and 150 mL closed with a white plastic child-resistant screw cap. The bottles are packed in cardboard boxes, and a measuring (device) spoon marked for doses of 2,5 mL and 5 mL is included in the secondary packaging.

Holder of Certificate of Registration

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This leaflet was last revised in

Approved 22 May 2023

Registration date: 16 May 2023

Registration number

57/5.7.1/0264