Patient Information Leaflet

Proposed Patient Information Leaflet

SCHEDULING STATUS

S2

DAZIT® TABLETS

Desloratadine 5 mg per tablet

Sugar free

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

DAZIT® TABLETS is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to use **DAZIT® TABLETS** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor, pharmacist.
- Do not share **DAZIT® TABLETS** with any other person.
- Ask your health care provider or pharmacist if you need any more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in the leaflet

- What **DAZIT® TABLETS** is and what it is used for
- What you need to know before you take **DAZIT® TABLETS**
- How to take **DAZIT® TABLETS**

- Possible side effects
- How to store **DAZIT® TABLETS**
- Contents of the pack and other information

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

DAZIT® TABLETS contains a medicine called desloratadine.

The active substance of **DAZIT® TABLETS** belongs to the group of medicines called antihistamines.

DAZIT® TABLETS are indicated for the relief of symptoms associated with seasonal allergic rhinitis (sneezing, rhinorrhoea and itching of the eyes, nose and throat).

DAZIT® TABLETS may also be used to relieve the symptoms associated with chronic idiopathic urticaria (itching, redness and number and size of hives).

2. What you need to know before you take DAZIT® TABLETS

Do not take DAZIT® TABLETS:

- If you are hypersensitive (allergic) to desloratadine or any of the ingredients (listed in **section 6**).
- If you are hypersensitive (allergic) to other medicines similar to **DAZIT® TABLETS** antihistamines for example loratadine.

Warnings and precautions

Take special care with **DAZIT® TABLETS:**

- If you have severe liver or kidney disease as the dosage you should take may need to be adjusted.
- If you suffer from the following diseases:
  - emphysema (shortness of breath, with a cough):
  - prostate problems;
  - narrow angle glaucoma (high pressure in the eye);
  - heart problems;
  - medical or family history of seizures

Inform your doctor before undergoing skin allergy test since **DAZIT® TABLETS** may interfere with the result of the test. **DAZIT® TABLETS** should be discontinued at least 48 hours before undergoing this test.

The use of **DAZIT® TABLETS** has been associated with the risk of weight gain.

Safety and efficacy of **DAZIT® TABLETS** have not been established for treatment periods in excess of 4 weeks.

Children and adolescents

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

Other medicines and DAZIT® TABLETS

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

Certain medicine can influence the mechanism of action of **DAZIT® TABLETS** and vice versa

Medicines known to influence the effect of **DAZIT® TABLETS** are medicines used for the treatment of:

- heartburn (such as cimetidine),
- anti-fungal (such as ketoconazole),
- antibiotic (such as erythromycin, azithromycin and clarithromycin),
- anti-depressant (such as fluoxetine) treatment.

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 health care provider for advice before taking this medicine.

Safety and efficacy in pregnancy and lactation has not been established. The use of **DAZIT® TABLETS** during pregnancy and breastfeeding is therefore not recommended.

Driving and using machines

DAZIT® TABLETS lack significant sedative effects. However some people may suffer sedation and blurred vision. Test your response before driving or performing complicated tasks.

3. How to take DAZIT® TABLETS

Always take **DAZIT® TABLETS** exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults older than 12 years of age: One tablet orally, once daily.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **DAZIT® TABLETS**.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks) your physician will recommend you for 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 physician may recommend you a longer term treatment.

For chronic idiopathic urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more DAZIT® TABLETS than you should

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

The symptoms reported for overdosage in adults and children: are headache, sleepiness and rapid heart rate.

If you forget to take DAZIT® TABLETS

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

If you stop taking DAZIT® TABLETS

Do not stop taking **DAZIT® TABLETS** unless your doctor tells you to do so. If you have further questions on the use of **DAZIT® TABLETS**, ask your doctor or pharmacist

4. Possible side effects

DAZIT® TABLETS can have side effects.

Not all side effects reported for **DAZIT® TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **DAZIT® TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Puffiness or swelling of the hands, feet, ankles, face, lips or tongue, mouth or throat, which may cause difficulty in swallowing or breathing, tightness in chest and wheezing, shortness of breath.

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

Less frequent:

- Changes in the way your heart beats, for example, if you notice it beating faster.

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

Tell your doctor if you notice any of the following:

Frequent:

- Headache.

- Pharyngitis (body aches or pain, congestion, cough, hoarseness, runny nose).
- Dry mouth.

Side-effects that require medical attention only if they become bothersome are the following:

Frequent:

- Headache and pharyngitis (body aches or pain, congestion, cough, hoarseness, runny nose).

Less frequent:

- Dizziness;
- Dry mouth;
- Difficult or painful menstruation;
- Acid or sour stomach;
- Unusual tiredness or weakness;
- Muscle aching or cramping;
- Nausea and vomiting;
- Blurred vision;
- Confusion;
- Nightmares;
- Sleepiness or drowsiness;
- Difficulty in sleeping;
- Seizures (epileptic fits);
- Agitation or increased feeling of restlessness (psychomotor hyperactivity);
- Diarrhoea;
- Stomach pain;
- Abnormal liver function tests;
- Rash or itchy skin;

- Hair loss;
- Extreme sensitivity to light and sunlight.

Frequency unknown:

- Yellowing of the skin and/or eyes (jaundice);
- Abnormal physical weakness or lack of energy (asthenia);
- Weight gain due to increased appetite.

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “6.04 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 **DAZIT® TABLETS**.

5. How to store DAZIT® TABLETS®

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light and moisture.
- 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® TABLETS contains

The active substance is desloratadine.

Each film-coated tablet contains 5 mg desloratadine.

The other ingredients are:

Meglumine, microcrystalline cellulose, Opadry blue 15B50612 (as coating agent), sodium starch glycolate, sodium stearyl fumarate, pregelatinised starch and starch.

What DAZIT® TABLETS looks like and contents of the pack

DAZIT® TABLETS are blue coloured circular shaped, biconvex, film-coated tablets debossed with “5” on one side and plain on the other side.

DAZIT® TABLETS are packed in white round HDPE bottle with polypropylene cap and liner. Each bottle contains 10 or 30 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd.

14 Lautre Road,

Stormill Ext.1,

Roodepoort, 1724,

South Africa.

This leaflet was last revised

28 January 2022

Registration number

41/5.7.1/0448