Approved Patient Information Leaflet

Aerzit 5

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

AERZIT 5 (film-coated tablets)

Read all of this leaflet carefully because it contains important information for you. AERZIT 5 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **AERZIT 5** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **AERZIT 5** 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.

1. WHAT AERZIT 5 CONTAINS:

AERZIT 5 is a film-coated tablet that contains 5 mg of desloratadine as the active ingredient.

Each film-coated tablet also contains: microcrystalline cellulose, maize starch, magnesium stearate, and colloidal anhydrous silica.

AERZIT 5 is sugar free.

2. AERZIT 5 IS USED FOR

AERZIT 5 is a non-sedating antihistamine, and it is used for the relief of symptoms associated with allergic rhinitis (hay fever) and for the relief of symptoms of

urticaria (hives of the skin).

BEFORE YOU TAKE AERZIT

Do not take AERZIT 5

- if you are hypersensitive (allergic) to desloratadine or any of the ingredients of
- if you are pregnant or breastfeeding
- if you are under 12 years

Take special care with AERZIT :

- if you have a history of kidney and/or liver disease, please advise your doctor or pharmacist as your dosage may need adjustment
- as it may cause a small number of individuals to become drowsy or less alert than they are normally

Taking AERZIT 5 with food and drink:

AERZIT 5 has no effect on food and may be taken with or without food.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you taking **AERZIT.**

Driving and using machinery:

AERZIT cause some people to become drowsy or less alert. Make sure you know

how you react to this medicine before you drive or use machines.

Important information about some of the ingredients of AERZIT:

AERZIT 5 is sugar free.

Taking other medicines with AERZIT 5

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

AERZIT 5 does not have any effect on other medication

3. HOW TO TAKE AERZIT 5

Always take **AERZIT 5** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share **AERZIT 5** with anyone else; it was prescribed for you.

The usual dose for **AERZIT 5** is:

Adults (≥ 12 years): One tablet orally, once a day regardless of mealtime.

Your doctor will tell you how long your treatment with **AERZIT 5** will last. Do not stop treatment early because you are feeling better.

If you have the impression that the effect **AERZIT 5** is too strong or too weak, tell your doctor or pharmacist.

If you forget to take AERZIT 5:

If you miss a dose of **AERZIT 5** , take 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 to make up for the forgotten individual doses.

If you take more AERZIT 5 than you should:

You may experience an increase in side effects and their frequency. 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 tablets with you, so that the doctor knows what you have taken.

4. POSSIBLE SIDE EFFECTS

AERZIT 5 can have side effects.

Not all side effects reported for **AERZIT 5** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AERZIT 5** , please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **AERZIT 5** and contact your doctor immediately or go the casualty department at your nearest hospital:

- anaphylaxis (allergic reaction) cough, difficulty swallowing, dizziness, fast heartbeat, hives, skin rash,
- itching, puffiness or swelling of the eyelids or around the eyes, face, lips of tongue,
- shortness of breath, tightness in chest, unusual tiredness or weakness, wheezing.

These are all very serious side effects. If you have them, you may have had a serious reaction to **AERZIT 5** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- headache
- pharyngitis (inflammation of the throat)
- body aches or pain
- congestion
- dryness or soreness of throat
- fever
- hoarseness
- runny nose
- tender swollen glands in neck and voice changes.

The following side effects may also occur less frequently:

- dizziness
- fatigue
- dry mouth

- drowsiness
- palpitations (fast heartbeat)
- abdominal pain
- nausea, vomiting, diarrhoea
- heartburn
- liver problems
- joint pain
- swollen joints
- muscle pain or stiffness, difficulty in moving, and muscle aching or cramping

Should your general health worsen while taking **AERZIT 5** , please consult your doctor, pharmacist or other health care professional for advice.

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

6. STORING AND DISPOSING OF AERZIT 5

Store at or below 25 ºC

Protect from light and moisture

Keep blisters in the carton until required for use

Do not store your medicine in the bathroom

Do not use **AERZIT 5** after the expiry date printed on the label, container or blister

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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

7. PRESENTATION OF AERZIT 5

AERZIT 5 are packed in blisters. The blisters are subsequently packed into cardboard boxes of 7 (1 strip of 7 tablets), 10 (1 strip of 10 tablets), 28 (2 strips of

14 tablets) or 30 (3 strips of 10 tablets) tablets.

The blisters are transparent PVC/PE/PVDC aluminium blisters and/or in transparent PVC/PCTFE/ aluminium blisters.

8. IDENTIFICATION OF AERZIT 5

AERZIT 5 : Blue, round, biconvex film coated tablets

9. REGISTRATION NUMBER

46/5.7.1/0493

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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11. DATE OF PUBLICATION

Date on the registration certificate: 18 February 2016