Approved Package Insert

AERZIT 5

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM

AERZIT 5 (film-coated tablets)

COMPOSITION:

AERZIT 5: Each tablet contains 5 mg desloratadine.

Inactive ingredients: colloidal anhydrous silica, maize starch, magnesium stearate and microcrystalline cellulose.

AERZIT 5 is sugar free

PHARMACOLOGICAL CLASSIFICATION:

A.5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:

Desloratadine is a non-sedating, long-acting tricyclic histamine antagonist with selective H_1-receptor histamine antagonist activity. It is a second generation H_1 antagonist and when given in therapeutic doses, is largely excluded from the brain (central nervous system), thus having non-sedating properties.

Pharmacokinetic properties:

Desloratadine is well absorbed from the gastro-intestinal tract.

Following oral administration, peak plasma concentrations are achieved in approximately 3 hours, and effects usually last 24 hours. The mean elimination half-life is approximately 27 hours. Desloratadine is 82 – 87 % bound to plasma proteins.

Desloratadine's absorption is not affected by food and the bioavailability of desloratadine is dose proportional over the range of 5 mg to 20 mg.

INDICATIONS:

AERZIT 5 film-coated tablets are indicated for the relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria.

CONTRAINDICATIONS:

Hypersensitivity to desloratadine or any ingredients of **AERZIT 5.**

Do not use if you are pregnant or breast-feeding.

WARNINGS AND SPECIAL PRECAUTIONS:

AERZIT 5 should be used with caution in patients with impaired hepatic and renal function. Monitoring of renal and hepatic function in such patients is appropriate.

Safety and efficacy of **AERZIT 5** in children under 12 years of age has not been established.

AERZIT 5 may interfere with skin tests using allergens

Effects on ability to drive and operate machinery

AERZIT 5 lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation.

It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system medication.

INTERACTIONS

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

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole, erythromycin, azithromycin, fluoxetine and cimetidine interaction trials.

PREGNANCY AND LACTATION

Safety and efficacy in pregnancy and lactation has not been established.

The use of **AERZIT 5** during pregnancy is therefore not recommended.

Desloratadine is excreted into breast milk, therefore the use of **AERZIT 5** is not recommended in breast-feeding women.

DOSAGE AND DIRECTIONS FOR USE

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

SIDE EFFECTS

The following side effects have been observed:

Central nervous system

Frequent: Headache

Less frequent: Dizziness, fatigue, somnolence, dry mouth

Cardiac disorders

Less frequent: Tachycardia, palpitations

Gastro-intestinal disorders

Less frequent: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea

Hepatobiliary disorders

Less frequent: Hepatic function abnormalities

Musculoskeletal and connective tissue disorders

Less frequent: Myalgia

Respiratory, thoracic and mediastinal disorders

Frequent: Pharyngitis, body aches or pain, congestion, cough, dryness or soreness of throat, fever, hoarseness, runny nose, tender, swollen glands in neck, voice changes

Immune system disorders

The following was reported but frequency is unknown: Anaphylaxis, cough, difficulty swallowing, dizziness, tachycardia, itching, puffiness or swelling of the eyelids or around the eyes, face, lips of tongue; shortness of breath, skin rash, tightness in chest, unusual tiredness or weakness, wheezing, pruritus, rash and urticaria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms:

(see WARNINGS AND SPECIAL PRECAUTIONS).

Treatment:

In the event of overdosage treatment should be symptomatic and supportive. Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric evaluation

IDENTIFICATION

AERZIT 5: Blue, round, biconvex film coated tablets.

PRESENTATION

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).

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

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

Protect from light and moisture

Keep blisters in the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN

REGISTRATION NUMBER

46/5.7.1/0493

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg, 2193

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date on the registration certificate: 18 February 2016