1. NAME OF THE MEDICINAL PRODUCT
Desloratadine Sandoz 5 mg Film Coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film-coated tablet contains 5 mg desloratadine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film-coated tablet.

Light blue, round shaped, biconvex film coated tablets, with “5” debossed on one side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- For the rapid relief of symptoms associated with seasonal allergic rhinitis (e.g., sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness).

- For the relief of symptoms associated with chronic idiopathic urticaria (e.g., relief of itching and the size and number of hives).

4.2 Posology and method of administration
Posology
Adults and adolescents (12 years of age and over): one 5 mg tablet once a day, with or without a meal.

Method of administration
Oral use.
The dose can be taken with or without food.

4.3 Contraindications
Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, or to loratadine.

4.4 Special warnings and precautions for use
Efficacy and safety of desloratadine tablets in children under 12 years of age have not been established.

Convulsions
Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

Renal insufficiency
In the case of severe renal insufficiency, desloratadine should be used with caution.

4.5 Interaction with other medicinal products and other forms of interaction
No clinically relevant interactions were observed with desloratadine tablets in which erythromycin or ketoconazole were co-administered.

Desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol.

However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of desloratadine in pregnant women. As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy.

Breast-feeding
Desloratadine has been identified in breastfed newborns/ infants of treated women. The effect of desloratadine on newborns/ infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from desloratadine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines
Desloratadine has no or negligible influence on the ability to drive and use machines. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable effects
Summary of the safety profile
The most frequent of adverse reactions reported were fatigue, dry mouth and headache. Other undesirable effects reported are listed in the following:

Metabolism and nutrition disorders
Not known: Increased appetite

Psychiatric disorders
Very rare: Hallucinations
Not known: Abnormal behaviour, aggression

Nervous system disorders
Common: Headache
Very rare: Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures

Cardiac disorders
Very rare: Tachycardia, palpitations
Not known: QT prolongation

Gastrointestinal disorders
Common: Dry mouth
Very rare: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea

Hepatobiliary disorders
Very rare: Elevations of liver enzymes, increased bilirubin, hepatitis
Not known: Jaundice

Skin and subcutaneous tissue disorders
Not known: Photosensitivity

Musculoskeletal and connective tissue disorders
Very rare: Myalgia

General disorders and administration site conditions
Common: Fatigue
Very rare: Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticaria)
Not known: Asthenia

Investigations
Not known: Weight increased

Paediatric population
Other undesirable effects reported during the post-marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

4.9 Overdose
The adverse event profile associated with overdose, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antihistamines for systemic use.
ATC code: R06A X27

Mechanism of action

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells.

5.2 Pharmacokinetic properties

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

Distribution

Desloratadine is moderately bound (83% - 87%) to plasma proteins.
There is no evidence of active substance accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded.

Desloratadine does not inhibit CYP3A4 and does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination

There was no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine. Grapefruit juice had no effect on the disposition of desloratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 Excipients

Maize starch
Microcrystalline cellulose
Hydroxypropyl methylcellulose
Purified water
Colloidal anhydrous silica
Vegetable oil, hydrogenated
Opadry blue

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Storage Condition

Store below 30°C.

7. DOSAGE FORM AND PACKAGING AVAILABLE

Desloratadine Sandoz 5mg Film Coated Tablet is available in pack size 10's.
10 tablets are either packed in Alu-Alu blisters or Aclar blisters, and then packed into an outer carton folding box.

8. PRODUCT REGISTRATION HOLDER

Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara KEN TTDI,

No. 37, Jalan Burhanuddin Helmi, Taman Tun Dr Ismail,
60000 Kuala Lumpur, Malaysia

9. DATE OF REVISION OF THE TEXT
Jul 2026