SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DAZIT
Each film-coated tablet contains:
Desloratadine.....5 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DAZIT is indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with:

- Allergic rhinitis
- Urticaria

4.2 Posology and method of administration

DAZIT is available in the strength of 5 mg only and may not be suitable for all dosage recommendations given below. Therefore, other suitable available strengths and/or dosage forms of desloratadine should be used in such cases.

Posology

Adults/Elderly people
The recommended dose of **DAZIT** is one tablet once a day.

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's

disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance.

In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

Paediatric population
There is limited data reported with the use of desloratadine in adolescents 12 through 17 years of age (see **section 4.8**).

The safety and efficacy of desloratadine in children below the age of 12 years have not been established.

Method of administration
DAZIT should be taken orally, 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

In the case of severe renal insufficiency, desloratadine should be used with caution (see **section 5.2**).

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children (see **section 4.8**), 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.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions have been reported with desloratadine tablets when co-administered with erythromycin or ketoconazole.

Paediatric population

Interaction studies have only been reported in adults.

Reportedly, desloratadine tablets when 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

A large amount of reported data on pregnant women indicate no malformative nor foeto/ neonatal toxicity of desloratadine. Reported animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see **section 5.3**). As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy.

Breastfeeding

Desloratadine has been reportedly 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 reported data available on male and female fertility.

4.7 *Effects on ability to drive and use machines*

Reportedly 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 with desloratadine are fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %).

Paediatric population

The most common adverse event reported in adolescent patients, 12 through 17 years of age was headache; this occurred in 5.9 % of patients treated with desloratadine and 6.9 % of patients receiving placebo.

Adverse Drug Reactions

The adverse reactions reported with desloratadine are listed in the following table. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with desloratadine
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.

A reported retrospective observational safety study indicated an increased incidence of new-onset seizure in patients 0 to 19 years of age when receiving desloratadine compared with periods not receiving desloratadine. Among children 0-4 years old, the adjusted absolute increase was 37.5 (95% Confidence Interval (CI) 10.5-64.5) per 100,000-person years (PY) with a background rate of new onset seizure of 80.3 per 100,000 PY. Among patients 5-19 years of age, the adjusted absolute increase was 11.3 (95% CI 2.3-20.2) per 100,000 PY with a background rate of 36.4 per 100,000 PY. (See **section 4.4**)

4.9 Overdose

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

Treatment

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.

Symptoms

Based on a reported multiple dose clinical trial, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H1 antagonist. *ATC Code:* R06A X27

Mechanism of action

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H1-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 from reported *in vitro* studies. 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. The clinical relevance of these observations remains to be confirmed.

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 reportedly consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was reported to be dose proportional over the range of 5 mg to 20 mg.

In a reported pharmacokinetic trial in which patient demographics were comparable to those of the general seasonal allergic rhinitis population, 4 % of the subjects achieved a higher concentration of desloratadine. This percentage may vary according to ethnic background. Maximum desloratadine concentration was about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours. The safety profile of these subjects was not different from that of the general population.

Distribution

Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant medicine 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 *in vivo*, and *in vitro* studies have reported that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination

In a reported single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine. In another reported study, grapefruit juice had no effect on the disposition of desloratadine.

Renally impaired patients

The pharmacokinetics of desloratadine in patients with chronic renal insufficiency (CRI) was compared with that of healthy subjects in a reported single-dose study and a reported multiple dose study. In the single-dose study, the exposure to desloratadine was approximately 2 and 2.5-fold greater in subjects with mild to moderate and severe CRI, respectively, than in healthy subjects. In the multiple-dose study, steady state was reached after Day 11, and compared to healthy subjects the exposure to desloratadine was ~1.5-fold greater in subjects with mild to moderate CRI and ~2.5-fold greater in subjects with severe CRI. In both reported studies, changes in exposure (AUC and C_{max}) of desloratadine and 3-hydroxydesloratadine were not clinically relevant.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Reported non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Reported non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The lack of carcinogenic potential was demonstrated in reported studies conducted with desloratadine and loratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate, maize starch, microcrystalline cellulose, croscarmellose sodium, povidone, ferric oxide yellow, ferric oxide red, purified talc, magnesium stearate, colloidal anhydrous silica, Hypromellose, macrogol and titanium dioxide.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store upto 30°C, protected from light.

6.5 Nature and contents of the container

Dazit 5are available in strips of 10 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

Sun Pharmaceutical Industries Limited

8. MARKETING AUTHORISATION NUMBER

14975

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE REGISTRATION

25/07/2026

10. DATE OF REVISION OF THE TEXT

25/07/2026