SUMMARY OF PRODUCT CHARACTERISTICS
DESONAL 5 (Desloratadine Tablets 5 mg)

1. NAME OF THE MEDICINAL PRODUCT

DESONAL 5 (Desloratadine Tablets 5 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg desloratadine.

Excipients with known effect:

Each tablet contains 60 mg lactose (as lactose monohydrate). For warnings, see section 4.4.

This medicinal product contains methyl paraben and propyl paraben. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Red coloured, round, biconcave film-coated tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

- Allergic rhinitis (intermittent and persistent).
- Urticaria.

4.2 Posology and method of administration

Adults and adolescents (12 years of age and over)

One tablet (5 mg) once daily, with or without food.

Intermittent allergic rhinitis (symptoms present fewer than 4 days per week or fewer than 4 weeks per year) should be managed in accordance with the evaluation of the patient's disease history; treatment may be discontinued after symptoms resolve and reinitiated upon reappearance. In persistent allergic rhinitis (symptoms present 4 or more days per week and for more than 4 weeks), continued treatment may be proposed during the allergen exposure period.

Paediatric population

The safety and efficacy of desloratadine film-coated tablets in children below the age of 12 years have not been established. The efficacy of desloratadine tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age; there is limited clinical trial efficacy experience in this age group.

Renal impairment

In the case of severe renal insufficiency, desloratadine should be used with caution (see section 4.4 and 5.2). No specific dose adjustment is recommended in mild to moderate renal impairment.

Method of administration

Oral. The tablets 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

Renal impairment

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

Seizures

Desloratadine should be administered with caution in patients with a medical or familial history of seizures, and mainly in young children, who may be more susceptible to developing new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment. A retrospective observational safety study indicated an increased incidence of new-onset seizure in patients 0 to 19 years of age receiving desloratadine compared with periods not receiving desloratadine. Among children 0–4 years old, the adjusted absolute increase was 37.5 (95% CI 10.5–64.5) per 100,000 person years (PY), with a background rate of 80.3 per 100,000 PY. Among patients 5–19 years, 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.

Alcohol

In a clinical pharmacology trial, 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. Caution is recommended if alcohol is taken concomitantly.

Lactose content

This product contains 60 mg lactose per tablet. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Paraben content

This medicinal product contains methyl paraben and propyl paraben, which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions were observed in clinical trials in which desloratadine was co-administered with erythromycin or ketoconazole. Desloratadine does not inhibit CYP3A4 in vivo, and in vitro studies have shown that the product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Caution is recommended if alcohol is taken concomitantly (see section 4.4).

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy

A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicates no malformative nor foeto/neonatal toxicity of desloratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of desloratadine during pregnancy.

Breast-feeding

Desloratadine has been identified in breast-fed 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 based on clinical trials. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, patients should be advised not to engage in activities requiring mental alertness (such as driving a car or using machinery) until they have established their own response to the medicinal product.

4.8 Undesirable effects

Summary of the safety profile

In clinical trials at the recommended dose of 5 mg daily, undesirable effects with desloratadine were reported in 3% of patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were fatigue (1.2%), dry mouth (0.8%) and headache (0.6%).

In a clinical trial with 578 adolescent patients (12 through 17 years), the most common adverse event was headache (5.9% desloratadine vs 6.9% placebo).

System Organ Class	Frequency	Adverse Reaction
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare / Not known	Hallucinations (very rare); abnormal behaviour, aggression, depressed mood (not known)
Nervous system disorders	Common / Very rare	Headache (common); dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures (very rare)
Eye disorders	Not known	Eye dryness
Cardiac disorders	Very rare / Not known	Tachycardia, palpitations (very rare); QT prolongation (not known)
Gastrointestinal disorders	Common / Very rare	Dry mouth (common); abdominal pain, nausea, vomiting, dyspepsia, diarrhoea (very rare)
Hepatobiliary disorders	Very rare / Not known	Elevations of liver enzymes, increased bilirubin, hepatitis (very rare); jaundice (not known)
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal disorders	Very rare	Myalgia
General disorders	Common / Very rare / Not known	Fatigue (common); hypersensitivity reactions including anaphylaxis, angioedema, dyspnoea, pruritus, rash, urticaria (very rare); asthenia (not known)
Investigations	Not known	Weight increased

Paediatric post-marketing data: QT prolongation, arrhythmia, bradycardia, abnormal behaviour and aggression have been reported with unknown frequency.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms
Based on a 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. The adverse event profile associated with overdosage is similar to that seen with therapeutic doses, but the magnitude of effects may be higher.

Treatment
Standard measures to remove unabsorbed active substance should be considered. 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: Antihistamines for systemic use. ATC code: R06AX27.

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors as the substance is excluded from entry to the central nervous system. Desloratadine also inhibits the release of pro-inflammatory cytokines (IL-4, IL-6, IL-8, IL-13) from human mast cells/basophils and inhibits the expression of the adhesion molecule P-selectin on endothelial cells.

In a multiple dose clinical trial in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. At 45 mg daily (nine times the clinical dose) for ten days, no QTc prolongation was seen. No clinically relevant changes in desloratadine plasma concentrations were observed in ketoconazole and erythromycin interaction trials.

Desloratadine does not readily penetrate the central nervous system. At the recommended dose of 5 mg daily, there was no excess incidence of somnolence compared to placebo. At 7.5 mg daily, psychomotor

performance was not affected. Co-administration with alcohol did not increase alcohol-induced impairment in performance.

5.2 Pharmacokinetic properties

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of administration. Maximum concentration is achieved after approximately 3 hours; terminal phase half-life is approximately 27 hours. Bioavailability is dose proportional over the range of 5–20 mg. In approximately 4% of subjects, desloratadine achieves a higher concentration (approximately 3-fold higher Cmax at approximately 7 hours, terminal half-life approximately 89 hours). The safety profile of these individuals was not different from the general population.

Distribution

Desloratadine is moderately bound (83–87%) to plasma proteins. No evidence of clinically relevant accumulation following once-daily dosing for 14 days.

Biotransformation

The enzyme responsible for the metabolism of desloratadine has not been identified. Desloratadine does not inhibit CYP3A4 or CYP2D6 in vivo and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination

Food (including high-fat, high-caloric meals) and grapefruit juice had no effect on the disposition of desloratadine. In patients with chronic renal insufficiency (CRI), exposure to desloratadine was approximately 2-fold (mild to moderate CRI) and 2.5-fold (severe CRI) greater than in healthy subjects. Changes in exposure were not considered clinically relevant. Desloratadine should be used with caution in severe renal insufficiency.

5.3 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient
1	Lactose monohydrate (excipient with known effect — 60 mg per tablet)
2	Maize starch
3	Microcrystalline cellulose
4	Povidone K-30
5	Methyl paraben (excipient with known effect)
6	Propyl paraben (excipient with known effect)
7	Purified water
8	Purified talc
9	Magnesium stearate
10	Colloidal anhydrous silica
11	Croscarmellose sodium
12	Hydroxypropylmethylcellulose (HPMC)
13	Isopropyl alcohol
14	Titanium dioxide (E171)
15	Iron oxide red (E172)
16	Propylene glycol

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Do not store above 30°C. Keep out of the reach and sight of children.

6.5 Nature and contents of container
PVC/foil blister packs. Pack size: 100 tablets (10×10 blisters).

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
NATIONAL PHARMACY LTD
Colchester Park, P.O. Box 17843-00500, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2026/CTD12764/27020

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10.01.2026

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