

PACKAGE LEAFLET
for medical use of a medicinal product

Eridez®

Qualitative and quantitative composition:

active substance: desloratadine;

1 oral dispersible tablet contains desloratadine 5 mg;

list of excipients: potassium polyacryline, potassium hydroxide, iron oxide red (E 172), magnesium stearate, croscarmellose sodium, aspartame (E 951), microcrystalline cellulose, mannitol (E 421), flavoring «Tutti Frutti» (contains propylene glycol (E 1520)).

Pharmaceutical form. Oral dispersible tablets.

Main physical and chemical properties: round flat tablets of red-brown color with beveled edges and embossed "5" on one side.

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

Pharmacological properties.

Pharmacodynamic properties.

Desloratadine is a long-acting non-sedative antihistamine that has a selective antagonistic effect on peripheral H₁-receptors. After oral administration, desloratadine selectively blocks peripheral histamine H₁-receptors. In *in vitro* studies, desloratadine has demonstrated its anti-allergic properties on endothelial cells. This was manifested by inhibition of the secretion of pro-inflammatory 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 adhesion molecules, such as P-selectin. The clinical significance of these observations still needs confirmation.

Studies have shown that, in addition to antihistaminic activity, desloratadine has anti-allergic and anti-inflammatory effects.

Desloratadine does not enter the central nervous system (CNS) and does not affect psychomotor function.

In patients with allergic rhinitis, desloratadine effectively relieves symptoms such as sneezing, runny nose and itching, as well as eye irritation, tearing and redness, and itchy palate. Desloratadine effectively controls symptoms for 24 hours.

Pharmacokinetic properties.

Absorption.

Plasma concentrations of desloratadine can be determined 30 minutes after administration.

Desloratadine is well absorbed, the maximum concentration is reached after about 3 hours.

Excretion.

The half-life is approximately 27 hours. The degree of accumulation of desloratadine corresponds to its half-life (approximately 27 hours) and frequency of administration once a day.

Linearity and nonlinearity.

The bioavailability of desloratadine was dose proportional in the range from 5 mg to 20 mg. Desloratadine is moderately bound to plasma proteins (83-87%). At a dose of desloratadine from 5 mg to 20 mg once a day for 14 days, no signs of clinically significant accumulation of the medicinal product were detected.

Food (fatty high-calorie breakfast) does not affect the pharmacokinetics of desloratadine. It was found that grapefruit juice also does not affect the pharmacokinetics of desloratadine.

Clinical particulars.

Therapeutic indications.

Elimination of symptoms associated with:

- allergic rhinitis;
- urticaria.

Contraindications.

Hypersensitivity to the active substance, to any of the excipients or to loratadine.

Interaction with other medicinal products and other forms of interaction.

No clinically relevant interactions were observed when desloratadine and erythromycin or ketoconazole tablets were co-administered.

Desloratadine, co-administered with alcohol, did not potentiate the negative effects of ethanol on psychomotor function.

Special warnings and precautions for use.

The medicinal product should be used with caution and under the supervision of a physician in case of severe renal insufficiency.

The medicinal product contains aspartame, so it can be harmful to people with phenylketonuria.

It should be used with caution in patients with a medical or family history of seizures, and mainly in young children who are more prone to new seizures during desloratadine treatment. Healthcare professionals may consider discontinuing desloratadine in patients who have seizures during treatment.

Fertility, pregnancy and lactation.

The safety of using the medicinal product during pregnancy has not been established, therefore, it is not recommended to use the medication during pregnancy.

Desloratadine passes into breast milk, so the medicinal product should not be taken by women during lactation.

Effects on ability to drive and use machines.

There was no decrease in performance in patients receiving desloratadine. However, patients should be informed that very rarely some people may have drowsiness, which may affect the ability to drive and use machines.

Posology and method of administration.

Adults and adolescents (over 12 years of age): 1 tablet once a day, with or without food, to relieve the symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria.

Treatment of intermittent allergic rhinitis (symptoms less than 4 days a week or less than 4 weeks) should be carried out taking into account the history: stop after symptoms disappear and recover after recurrence. In case of persistent allergic rhinitis (symptoms for more than 4 days a week or more than 4 weeks) it is necessary to continue treatment throughout the entire period in contact with the allergen.

Method of administration.

Immediately before taking the blister, open and remove carefully, without crushing, the tablet, which is dispersed in the oral cavity, so that it does not crumble. Put the tablet in your mouth, where it will disintegrate immediately. Water or other liquid is not required to swallow the tablet. The dose should be taken immediately after opening the blister.

Children.

In this dosage form, the medicinal product is intended for use in children over 12 years of age.

Overdose.

In case of overdose, standard measures aimed at removing the unabsorbed active substance are indicated. Symptomatic and supportive treatment is recommended. During studies with the use of a multiply increased dose in adults and adolescents who were given up to 45 mg of desloratadine (the dose is 9 times higher than the therapeutic dose), no clinically significant effect was found.

Desloratadine is not excreted by hemodialysis, it is unknown whether it is removed by peritoneal dialysis.

Undesirable effects.

There is a risk of psychomotor hyperactivity (abnormal behavior) associated with the use of desloratadine (which can manifest itself in the form of anger and aggression, as well as agitation).

Adverse events have been ranked under headings of frequency using the following convention: very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1000$, $< 1/100$); rare ($\geq 1/10000$, $< 1/1000$); very rare ($< 1/10000$), frequency unknown (cannot be calculated according to available data).

Gastrointestinal disorders: common - dry mouth; very rare - abdominal pain, nausea, vomiting, dyspepsia, diarrhea.

Hepatobiliary disorders: very rare - an increased in the levels of liver enzymes, increased bilirubin, hepatitis; frequency unknown - jaundice.

Metabolism and nutrition disorders: frequency unknown - increased appetite.

Nervous system disorders: common - headache; very rare - dizziness, drowsiness, insomnia, psychomotor agitation, convulsions.

Psychiatric disorders: very rare - hallucinations; frequency unknown - abnormal behavior, aggression.

Cardiac disorders: very rare - tachycardia, palpitations; frequency unknown - QT prolongation, supraventricular tachyarrhythmia.

Skin and subcutaneous tissue disorders: frequency unknown - photosensitivity.

Musculoskeletal and connective tissue disorders: very rare - myalgia.

General disorders: common - increased fatigue; very rare - hypersensitivity reactions (anaphylaxis, Quincke's edema, shortness of breath, itching, rash and urticaria); frequency unknown - asthenia.

Study: frequency unknown - increased of body weight.

Reported suspected adverse reactions.

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

Shelf life. 3 years.

Special precautions for storage.

Store in the original package at a temperature below 25 °C.

Keep out of the reach of children.

Nature and contents of container.

Oral dispersible tablet, 5 mg; 10 tablets in a blister, 1 blister in a pack.

Category of release. Non-prescription medicine.

Manufacturer. Genepharm S.A..

The manufacturer's location and address of the place of business.
18km Marathon Avenue, Pallini Attici, 15351, Greece.

Marketing authorisation holder. PrJSC “Pharmaceutical firm “Darnitsa”.

The Marketing authorisation holder's location and address of the place of business.
Ukraine, 02093, Kyiv, 13 Boryspilska street.

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