

**APPROVED**  
**By the Order of the Ministry of**  
**Health of Ukraine**  
**26.04.2018 No. 799**  
**Marketing Authorization**  
**No. UA/12919/01/01**

**VARIATIONS APPLIED**  
**By the Order of the Ministry of**  
**Health of Ukraine**  
**06.07.2018 No. 1270**

**PACKAGE LEAFLET**  
for medical use of a medicinal product

**Eridez-Darnitsa**

***Qualitative and quantitative composition:***

*active substance:* desloratadine;

1 tablet contains 5 mg of desloratadine;

*list of excipients:* calcium hydrogen phosphate, microcrystalline cellulose, lactose monohydrate, corn starch, magnesium stearate, opadray 85 F blue.

**Pharmaceutical form.** Coated tablet.

*Main physical and chemical properties:* bevelled, round, blue biconvex coated tablets

**Pharmacotherapeutic group.** Antihistamines for systemic use. ATC code R06A X27.

***Pharmacological properties.***

*Pharmacodynamics properties.*

Desloratadine is a non-sedating histamine antagonist with selective peripheral H<sub>1</sub>-receptor antagonist activity. Desloratadine is the primary active metabolite of loratadine. After oral administration, desloratadine selectively blocks peripheral histamine H<sub>1</sub>-receptors and does not cross the blood-brain barrier.

In addition to antihistamine activity, desloratadine has anti-allergic and anti-inflammatory effects. It was found that desloratadine inhibits the cascade of various reactions that underlie the development of allergic inflammation, namely: release 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 the adhesion molecules, such as P-selectin. The clinical relevance of these observations remains to be confirmed.

In a multiple dose clinical trials, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically significant relevant cardiovascular effect was observed. In a clinical pharmacology trial, in which desloratadine was administered at a dose of 45 mg daily (10 times the maximum daily clinical dose) for 10 days, no prolongation of the QT interval was observed.

In patients with allergic rhinitis, desloratadine was effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular irritation, tearing and redness, and itching of palate. Desloratadine effectively controlled symptoms for 24 hours.

Desloratadine does not readily penetrate the central nervous system. In controlled clinical trials, at the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo.

Desloratadine given at a single daily dose of 7.5 mg did not affect psychomotor performance and did not cross the blood-brain barrier.

Desloratadine was effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities that limited the symptoms.

Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions. Because histamine release is a causal factor in all forms of urticaria diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, other than chronic idiopathic urticaria.

In two placebo-controlled six-week studies in patients with chronic idiopathic urticaria, desloratadine was effective in relieving pruritus and decreasing the number and size of hives by the end of the first dosing interval. In each study, the effect was sustained over the 24-hour dosing interval. An improvement in pruritus of more than 50 % was observed in 55 % of patients treated with desloratadine, compared with 19 % of patients treated with placebo. Treatment with the medicinal product also significantly reduced interference with sleep and daytime activity.

#### *Pharmacokinetic properties.*

Desloratadine plasma concentrations can be detected within 30 minutes of administration. The maximum concentration of desloratadine in blood plasma 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 frequency of application (1 time per day). The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

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.

Food (fatty high-calorie breakfast) or grapefruit juice were no effect on the distribution of desloratadine.

#### **Clinical particulars.**

##### ***Therapeutic indications.***

Relief of symptoms associated with:

- allergic rhinitis (see section "Pharmacological properties");
- urticaria (see section "Pharmacological properties").

##### ***Contraindications.***

Hypersensitivity to the active substance or to any of the excipients of the medicinal product or to loratadine.

##### ***Interaction with other medicinal products and other forms of interaction***

*Be sure to tell your doctor if you are taking any other medicines.*

No clinically relevant changes in desloratadine plasma concentrations were observed with repeated co-administration with ketoconazole, erythromycin, azithromycin, fluoxetine, and cimetidine.

In the clinical pharmacological trial, the medicinal product taken concomitantly with alcohol, did not potentiate the negative effects of ethanol on psychomotor function. However, cases of alcohol intolerance and alcohol intoxication have been reported during the post-marketing use. Therefore, caution is recommended if alcohol is taken during treatment with Eridez-Darnitsa.

##### ***Special warnings and precautions for use.***

In patients with high renal insufficiency, Eridez-Darnitsa should be used under the supervision of a physician.

Desloratadine should be administered with caution in patients with a history of seizures. Children may be more sensitive to the development of a new seizure under desloratadine treatment. The healthcare providers may consider discontinuing desloratadine treatment in patients who experience a seizure while on treatment.

If a patient has an intolerance to certain sugars, consult a doctor before taking this medicine.

### *Fertility, pregnancy and lactation*

The safety of Eridez-Darnitsa in pregnant women has not been established, so it is not recommended to prescribe the medicinal product during pregnancy. Desloratadine passes into breast milk, so the medicinal product should not be prescribed to women during breastfeeding.

### *Effects on ability to drive and use machines*

There are no special studies on the effect of the medicinal product on the ability to drive a car or work with mechanisms. However, patients should be warned that in very rare cases, people experience drowsiness, which may affect their ability to drive and use complex equipment.

### ***Posology and method of administration.***

Eridez-Darnitsa- is intended for oral administration. Adults and children 12 years of age and older should take 1 tablet (5 mg) once daily with or without food to relieve symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria. The tablet should be swallowed whole with water.

The duration of treatment is determined by the severity and course of the disease.

Treatment of intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history: 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.

### *Children.*

The efficacy and safety of desloratadine tablets for children under 12 years of age have not been studied.

### ***Overdose.***

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended. No clinically relevant adverse reactions were observed in clinical trials in which desloratadine was administered at doses of 45 mg (9 times the recommended dose). Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

### ***Undesirable effects.***

In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria, 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 %).

*Children.* 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). Undesirable effects reported during the post marketing period (an unknown frequency): QT prolongation, arrhythmia and bradycardia.

Summary table of frequency of adverse reactions.

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 ( $< 1/10000$ ) and unknown.

<b>Classes and organ systems</b>	<b>Frequency of occurrence</b>	<b>Adverse reactions</b>
<i>Psychiatric disorders</i>	<i>very rare</i>	hallucinations
<i>Nervous system disorders</i>	<i>common:</i>	headache

	<i>very rare</i>	dizziness, drowsiness, insomnia, psychomotor hyperactivity, convulsions
<i>Cardiac disorders</i>	<i>very rare</i>	tachycardia, rapid heartbeat
	<i>unknown</i>	QT interval prolongation supraventricular tachyarrhythmia
<i>Gastrointestinal disorders</i>	<i>common:</i>	dry mouth.
	<i>very rare</i>	abdominal pain, nausea, vomiting, dyspepsia, diarrhea
<i>Hepatobiliary disorders</i>	<i>very rare</i>	increased liver enzymes, elevated bilirubin, hepatitis
	<i>unknown</i>	jaundice
<i>Musculoskeletal and connective tissue disorders:</i>	<i>very rare</i>	myalgia
<i>Skin and subcutaneous tissue disorders</i>	<i>unknown</i>	photosensitization
<i>General disorders</i>	<i>common</i>	increased fatigue
	<i>very rare</i>	hypersensitivity reactions (such as anaphylaxis, Quincke's edema, shortness of breath, itching, rash and urticaria)
	<i>unknown</i>	asthenia

*If any undesirable effects occur, consult a doctor.*

***Shelf life*** 2 years.

Do not use this medicinal product after the expiry date which is indicated on the package.

### **Special precautions for storage**

Keep out of reach of children at a temperature not above 25°C.

### **Nature and contents of container.**

10 tablets in a blister container; 1 or 2 or 3 blister containers in a package.

### **Category of release**

Without a prescription.

### **Manufacturer.**

PrJSC "Pharmaceutical firm "Darnitsa".

### **The manufacturer's location and address of the place of business.**

13, Boryspilska Street, Kyiv, 02093, Ukraine.

### **Date of the last revision.**

06.07.2018