TADES

Instructions for the medicinal product

Trade name: Tades.
International nonproprietary name: Desloratadine.
Dosage form: Film coated tablets.
Composition: Desloratadine 5 mg
Colour: Indigo Carmine and Titanium Dioxide
Excipients q.s.
Pharmacotherapeutic group: Antihistamine H1 antagonist.
ATC Code: R06AX27.
Pharmacologic property:
Pharmacodynamics:
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 because the substance is excluded from entry to the central nervous system.
Desloratadine has demonstrated antiallergic properties from 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.
Pharmacokinetics:
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.
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 can not be fully excluded. Desloratadine does not inhibit CYP3A4 in vivo, and in vitro studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.
Indications for use:
Indicated in adults and adolescents aged 12 years or older for the relief of symptoms associated with:
- Allergic rhinitis;
- Urticaria.

Contraindications:
- Hypersensitivity to the active substance, to any of the excipients or to loratadine;
- Pregnancy and Lactation;
- Children below the age of 12 years (The safety and efficacy have not been established. No data are available.)

Should be used with caution: In the case of severe renal insufficiency
Pregnancy and lactation:
It is preferable to avoid the use of desloratadine during pregnancy.
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.
Dosage and Direction for use:
Oral use.
The dose can be taken with or without food.
Adults and adolescents (12 years of age and over):
The recommended dose 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.
Side effects:
Psychiatric disorders: Very rare - Hallucinations.
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, diarrhea.
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.
Overdose:
Symptoms: The adverse event profile associated with overdosage, is similar to that seen 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.
Drug interactions:
No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered
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. Therefore, caution is recommended if alcohol is taken concomitantly.
Cautions:
Effects on ability to drive and use machines:
Tades 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, 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
Presentation:
1x10 PVC Blister in a monocarton with instruction for use.
Storage:
Keep in dry place protected from light at temperature below 30°C. Keep out of reach of children.
Expiry date:
Labeled. Do not use after expiry date.
Distribution Condition:
Prescription only medicine (POM).