pharmaniaga®

Xynoz 5 mg

Desloratadine Tablet

COMPOSITION

Each film coated tablet contains Desloratadine 5 mg.

PRODUCT DESCRIPTION

Light blue, round film-coated tablet marked with 'D5' on one side and plain on the other.

PHARMACODYNAMICS

Desloratadine is a non-sedating long-acting histamine antagonist with potent, selective peripheral H1-receptor antagonist activity. Desloratadine has demonstrated antiallergic, antihistaminic and anti-inflammatory activities. After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors because the drug is effectively excluded from entry to the central nervous system.

Based on reported data, desloratadine inhibits the broad cascade of events that initiate and propagate allergic inflammation, including:

- the release of proinflammatory cytokines including IL-4, IL-6, IL-8, IL-13;
- the release of important proinflammatory chemokines such as RANTES (Regulated upon Activation, Normal T-cell Expressed and Secreted);
- superoxide anion production by activated polymorphonuclear neutrophils;
- eosinophil adhesion and chemotaxis;
- the expression of the adhesion molecules such as P-selectin;
- IgE-dependent release of histamine, prostaglandin (PGD2), and leukotriene (LTC4);
- the acute allergic bronchoconstrictor response and allergic cough in animal models.

At the recommended adult dose of 5 mg daily, there was no excess incidence of somnolence and not affect standard measures of flight performance including exacerbation of subjective sleepiness or task related to flying. Also, Xynoz tablet at a dose of 7.5 mg daily does not affect psychomotor performance. Based on reported data, at a dose 20 mg daily for 14 days resulted in no statistical or clinical cardiovascular effect. At a dose 45 mg daily for 10 days, no prolongation of the QTc interval was reported.

No clinically relevant changes in desloratadine plasma concentrations were observed when taken concomitantly with ketoconazole, erythromycin, azithromycin, fluoxetine and cimetidine.

Based on literature, co-administration of alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness. No significant differences were found in the psychomotor test results, whether administered alone or with alcohol.

In adult and adolescent patients with allergic rhinitis, Xynoz tablet was effective in relieving symptoms such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness, and itching of palate. Xynoz tablet effectively controlled symptoms for 24 hours.

Based on the available data, Xynoz tablet was effective in relieving pruritis and decreasing the size and number of hives as early as 1 day after initiation of treatment in adults and adolescence with chronic idiopathic urticaria (CIU). The effects were sustained over the 24-hour dosing interval. Treatment with Xynoz tablet also improved sleep and daytime function, as measured by reduced interference with sleep and routine daily activities.

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

PHARMACOKINETICS

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 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.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no reported data on desloratadine accumulation following once daily dosing (5 mg to 20 mg) for 14 days.

Biotransformation
Desloratadine does not inhibit CYP3A4 or CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination
There was no effect of food (high-fat, high caloric breakfast) and grapefruit juice on the disposition of desloratadine.

INDICATIONS

Xynoz tablet is indicated for the rapid relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/ stuffiness, as well as ocular itching, tearing and redness.

Xynoz tablet is also indicated for the symptomatic relief of itching and the size and number of hives which is associated with chronic idiopathic urticaria.

RECOMMENDED DOSAGE

Adults and Adolescents (12 years of age and older): One tablet once a day regardless of mealtime. The dose can be taken with or without food.

ROUTE OF ADMINISTRATION

Oral.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Efficacy and safety of Xynoz tablet in children under 12 years of age have not been established.

In the case of severe renal insufficiency, Xynoz tablet should be used with caution. Desloratadine should be administered with caution in patients with medical or family history of seizures, and mainly young children, 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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Based on existing data, no clinically relevant interactions were observed when desloratadine co-administered with ketoconazole, erythromycin, azithromycin, fluoxetine and cimetidine.
There was no effect of food or grapefruit juice on the disposition of desloratadine. Xynoz tablet taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol. However, caution is recommended if alcohol is taken concomitantly.

PREGNANCY AND LACTATION

Pregnancy
Xynoz tablet is not to be used during pregnancy unless the potential benefits outweigh the risks.

Breast-feeding
The use of Xynoz tablet is not recommended in breast-feeding women.

ADVERSE REACTIONS

The most frequent of adverse reactions reported were fatigue, dry mouth and headache.

Paediatric population
Based on existing data, the most common adverse reaction was headache. Other adverse reactions reported for paediatric patients with an unknown frequency are QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation
Gastrointestinal disorders	Common Very rare	Dry mouth Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare Not known	Elevations of liver enzymes, increased bilirubin, hepatitis Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorders and administration site conditions	Common Very rare Not known	Fatigue Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria) Asthenia
Investigations	Not known	Weight increased

OVERDOSE AND TREATMENT

No clinically relevant effects were observed for desloratadine doses up to 45 mg. The adverse event profile associated with overdosage is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No effects on the ability to drive and use machines have been observed. 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.

STORAGE CONDITIONS

Store below 30°C.
Store in the original package.

PACK SIZE

In boxes of 1 blister x 10 tablets, 10 blisters x 10 tablets

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NO.
MAL22046026AZ

KEEP MEDICINE OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

CONTROLLED MEDICINE
UBAT TERKAWAL

For further information, please consult your doctor or your pharmacist.

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Lt-308.01 PRODUCT REGISTRATION HOLDER AND MANUFACTURER

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