PACKAGE INSERT
DELOHIST 5
(Desloratadine Film Coated tablets 5 mg)

1. NAME OF THE MEDICINAL PRODUCT

DELOHIST 5 (Desloratadine Film Coated Tablets 5 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains desloratadine Ph.Eur 5 mg.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Light blue colored, 6.6 mm round, biconvex, film coated tablets, debossed with 'D' on one side and '5' on other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Desloratadine Tablets are 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.

Desloratadine Tablets are also indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives.

4.2 Posology and method of administration

Adults and Adolescents (12 years of age and older): One Desloratadine Tablets 5 mg film-coated tablet once a day regardless of mealtime. For oral use.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Efficacy and safety of Desloratadine Tablets in children under 12 years of age have not been established.

Desloratadine should be administered with caution in patients with a medical or family history of seizures. In particular, young children 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.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions with Desloratadine were observed in clinical trials (see section on Pharmacodynamic properties). There was no effect of food or grapefruit juice on the disposition of desloratadine. Desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol

4.6 Fertility, pregnancy and lactation

No overall effect on rat fertility was observed with desloratadine at an exposure that was 34 times higher than the exposure in humans at the recommended clinical dose.

No teratogenic or mutagenic effects were observed in animal trials with desloratadine. Since no clinical data on exposed pregnancies are available with desloratadine, the safe use of Desloratadine during pregnancy has not been established. Desloratadine is not to be used during pregnancy unless the potential benefits outweigh the risks.

Desloratadine is excreted into breast milk; therefore the use of Desloratadine is not recommended in breast-feeding women.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

In clinical trials in a range of indications including AR and CIU, at the recommended dose of 5 mg daily, undesirable effects with Desloratadine tablets were reported in 3 % of patients in excess of those treated with placebo. The most frequent adverse events reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %), and headache (0.6 %).
Very rare cases of hypersensitivity reactions, including anaphylaxis and rash, have been reported during the marketing of desloratadine. In addition, cases of tachycardia, palpitations, psychomotor hyperactivity, somnolence, seizures, elevations of liver enzymes, hepatitis, increased bilirubin and increased appetite have been reported very rarely.

4.9 Overdose

In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Based on a multiple dose clinical trial in adults and adolescents, in which up to 45 mg of desloratadine was administered (9 times the clinical dose), no clinically relevant effects were observed.

Desloratadine is not eliminated by hemodialysis; it is not known if it is eliminated by peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
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 activity. After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors because the drug is effectively excluded from entry to the central nervous system (CNS).

In addition to antihistaminic activity, desloratadine has demonstrated antiallergic and anti- inflammatory activity from numerous in vitro (mainly conducted on cells of human origin) and in vivo studies. These studies have shown that 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.

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. In a clinical pharmacologic trial, in which desloratadine was administered at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of the QTc interval was seen.

Desloratadine does not readily penetrate the central nervous system. At the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo. Desloratadine even at a dose of 7.5 mg daily did not affect psychomotor performance in clinical trials. A single dose of desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole, erythromycin, azithromycin, fluoxetine and cimetidine interaction trials.

In clinical pharmacologic trials, 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 between desloratadine and placebo groups, whether administered alone or with alcohol.

In adult and adolescent patients with allergic rhinitis (AR), Desloratadine tablets were 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. Desloratadine tablets effectively controlled symptoms for 24 hours.

In two 4-week trials in patients with seasonal allergic rhinitis (SAR) and concurrent asthma, desloratadine was shown to be effective in reducing the symptoms of SAR (rhinorrhea,

nasal congestion, nasal itching and sneezing, itching/burning eyes, tearing/watering eyes, redness of eyes, and itching of ears or palate) and asthma (coughing, wheezing, difficulty breathing), and decreasing beta-agonist use. FEV1 was not altered in the desloratadine or placebo treatment groups.

In trials conducted in adults and adolescents with chronic idiopathic urticaria (CIU), Desloratadine tablets were effective in relieving pruritus and decreasing the size and number of hives as early as 1 day after initiation of treatment. In each trial, the effects were sustained over the 24 hour dosing interval. Treatment with Desloratadine tablets also improved sleep and daytime function, as measured by reduced interference with sleep and routine daily activities.

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

5.2 Pharmacokinetic properties
Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine 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. In adults and adolescents, 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 drug accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore some interactions with other drugs can not be fully excluded. In vivo studies with specific inhibitors of CYP3A4 and CYP2D6 have shown that these enzymes are not important in the metabolism of desloratadine. Desloratadine does not inhibit CYP3A4 or CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

In a single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (high- fat, high caloric breakfast) on the disposition of desloratadine. In another study, grapefruit juice had no effect on the disposition of desloratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Cellulose Microcrystalline
Starch Pregelatinized
Silica Colloidal Anhydrous
Magnesium Stearate

Coating:
Opadry 03A30735 Blue

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. Protect from light and protect from moisture

6.5 Nature and contents of container

Clear PVC/PE/PVdC-Aluminium foil blister of 10’s (1 or 3 or 10 x 10’s Blisters)

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

AUROBINDO

AUROBINDO PHARMA LIMITED (UNIT XV),
Plot No: 17 A,
E Bonangi Village,.
Parawada Mandal, Anakapalli District,
Anakapalli, 531021
INDIA

8. PRODUCT REGISTRATION HOLDER IN MALAYSIA

Synerrv Sdn Bhd,
SO-29-2, Menara 1, KL ECO City, Jalan Bangsar, KG Haji Abdullah Hukum, 59200 Kuala Lumpur Wilayah Persekutuan Kuala Lumpur, Malaysia.

9. DATE OF REVISION OF THE TEXT

Sept 2025

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