November 2023

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Deslorat 0.5mg Syrup

2. QUALTITIVE AND QUANTITATIVE COMPOSITION
Each 100 ml Syrup contains 0.5 mg Desloratadine
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Syrup.
Clear orange pach flvored solution having a sweet palatable taste

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:
Deslorat is indicated for the relief of symptoms associated with:
- Allergic rhinitis.
- Urticaria

4.2 Posology and Method of administration:
Method of administration
Deslorat may be taken without regard to mealtime for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria.
Deslorat tablets:
Adults and adolescents (12 years of age and over): one tablet once a day,
Deslorat Syrup:
The prescriber should be aware that most cases of rhinitis below 2 years of age are of infectious origin and there are no data supporting the treatment of infectious rhinitis with Deslorat.
Children 2 through 5 years of age: 2.5 ml (half teaspoonful) Deslorat syrup once a day.
Children 6 through 11 years of age: 5 ml (one teaspoonful) Deslorat syrup once a day.
In adults and adolescents (12 years of age and over): 10 ml (two teaspoonfuls) Deslorat Syrup 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.
There is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age

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

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

Deslorat syrup: Not to be used for children below 2 years old.

In children below 2 years of age, the diagnosis of allergic rhinitis is particularly difficult to distinguish from other forms of rhinitis. The absence of upper respiratory tract infection or structural abnormalities, as well as patient history, physical examinations, and appropriate laboratory and skin tests should be considered.

Approximately 6 % of adults and children 2- to 11-year old are phenotypic poor metabolisers of desloratadine and exhibit a higher exposure. The safety of desloratadine in children 2- to 11-years of age who are poor metabolisers is the same as in children who are normal metabolisers. The effects of desloratadine in poor metabolisers < 2 years of age have not been studied.

In the case of severe renal insufficiency, Deslorat should be used with caution.

Deslorat tablets contains lactose monohydrate: thus, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Deslorat syrup contains sorbitol; thus, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction:

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.

4.6 Fertility,Pregnancy and lactation:

Desloratadine was not teratogenic in animal studies. The safe use of the medicinal product during pregnancy has not been established. The use of Deslorat during pregnancy is therefore not recommended.

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

4.7 Effects on ability to drive and use machines:

No impairment occurred in patients receiving desloratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects:

In adults and adolescents the most frequent adverse events reported with desloratadine were: fatigue, dry mouth and headache.

In infants and toddlers aged 6 to 23 months, the most frequent adverse events reported were diarrhea, fever and insomnia.

No adverse events were seen in subjects between 6 and 11 years of age following a single 2.5 mg dose of desloratadine syrup.

Other undesirable effects reported very rarely were: Psychiatric disorders: Hallucinations , Nervous system disorders: Dizziness, somnolence, insomnia,

psychomotor hyperactivity, seizures , Cardiac disorders: Tachycardia, palpitations, Gastrointestinal disorders: Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea, Hepatobiliary disorders: Elevations of liver enzymes, increased bilirubin, hepatitis, Musculoskeletal and connective tissue disorders: Myalgia, General disorders: Hypersensitivity reactions: (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria)

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 which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.
Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: antihistamines – H1 antagonist- ATC CODE: R06AX27
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. The clinical relevance of these observations remains to be confirmed.
Desloratadine does not readily penetrate the central nervous system.
Co-administration with alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness.
No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole and erythromycin interaction trials.
In adults and adolescents patients with allergic rhinitis, Desloratadine tablets was effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Desloratadine effectively controlled symptoms for 24 hours.
Desloratadine tablets 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.
Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions, since the underlying pathophysiology is similar, regardless of etiology, and because chronic patients can be more easily recruited prospectively. Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic

idiopathic urticaria, as advised in clinical guidelines.
Efficacy of desloratadine has not been investigated in paediatric trials in children less than 12 years of age.

5.2 Pharmacokinetic properties:
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.
In a pharmacokinetic trial on desloratadine in which patient demographics were comparable to those of the general seasonal allergic rhinitis population, 4 % of the subjects achieved a higher concentration of desloratadine. This percentage may vary according to ethnic background. Maximum desloratadine concentration was about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours. The safety profile of these subjects was not different from that of the general population.
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant active substance accumulation following once daily adult and adolescent 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 medicinal products cannot 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.
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.
In a series of pharmacokinetic and clinical trials, 6 % of the subjects reached a higher concentration of desloratadine. The prevalence of this poor metaboliser phenotype was comparable for adult (6 %) and paediatric subjects 2- to 11-year old (6 %), and greater among Blacks (18 % adult, 16 % paediatric) than Caucasians (2 % adult, 3 % paediatric) in both populations.
In a multiple-dose pharmacokinetic study conducted with the tablet formulation in healthy adult subjects, four subjects were found to be poor metabolisers of desloratadine. These subjects had a Cmax concentration about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours.
Similar pharmacokinetic parameters were observed in a multiple-dose pharmacokinetic study conducted with the syrup formulation in paediatric poor metaboliser subjects 2- to 11-year old diagnosed with allergic rhinitis. The exposure (AUC) to desloratadine was about 6-fold higher and the Cmax was about 3 to 4 fold higher at 3-6 hours with a terminal half-life of approximately 120 hours. Exposure was the same in adult and paediatric poor metabolisers when treated with ageappropriate doses. The overall safety profile of these subjects was not different from that of the general population. The effects of desloratadine in poor metabolizers < 2

years of age have not been studied.
In a single dose, study of desloratadine, the tablet and the syrup formulations were found to be bioequivalent.
In separate single dose studies, at the recommended doses, paediatric patients had comparable AUC and Cmax values of desloratadine to those in adults who received a 5 mg dose of desloratadine syrup.
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 :
Sucrose
Sorbitol 70% solution
Propylene glycol
Sodium citrate
Citric acid
Sodium benzoate
Disodium edetate,
Fd&c yellow no.6
Peach flavor
Purified water.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 Years

6.4 Special Precautions for Storage:
Store at a temperature not exceeding 30 °C.
Keep out of the reach of children.

6.5 Nature and contents of container
Carton box containing PET bottle of 100 ml and insert leaflet.

7. MARKETING AUTHORISATION HOLDER
Eva Pharma for Pharmaceuticals & Medical Appliances, Giza, Egypt

8. MARKETING AUTHORISATION NUMBER(S)
07695/080404/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorization: 13-6-2018

Date of latest renewal: 8-08-2022

10. DATE OF REVISION OF THE TEXT

24-October-2023

11. REFERENCE