Fernilar

Desloratadine

0.5mg/1ml syrup.
5mg Film Coated Tablets.

1-Company name:

Egyptian Group For Pharmaceutical Industries. (EGPI)

2-Trade name :

Fernilar 0.5mg/1ml syrup.
Fernilar 5mg Film Coated Tablets.

3-Generic name :

Desloratadine 0.5 mg/1ml.
Desloratadine 5mg.

4-Composition:

Each 1ml syrup contains:
Active Ingredients:
Desloratadine 0.5 mg.
Inactive Ingredients:
Citric acid anhydrous, Sodium citrate anhydrous, Propylene glycol, Sorbitol 70% solution, Sodium benzoate, Sucrose, EDTA sodium, Saccharin sodium, Sunset yellow 85%, Orange flavour and Purified water.

Each Film Coated Tablet contains:
Active Ingredients:
Desloratadine 5mg.
Inactive Ingredients:
Dibasic calcium phosphate dihydrate, Microcrystalline cellulose, Maize Starch, Talc, Hypromellose, Polyethylene glycol 6000, Titanium dioxide, Polysorbate 80 (Tween 80), Talc, Indigo carmine lake, Isopropanol.

5-Pharmaceutical form:

Syrup & Film Coated Tablets.

6-Pharmacological action:

Desloratadine is a long-acting non sedating tricyclic histamine antagonist with selective *H_1-receptor* antagonist activity. Receptor binding data indicates that at a concentration of 2-3 ng/mL (7 nanomolar), desloratadine shows significant interaction with the human *H_1-receptor*. Desloratadine inhibit histamine release from human mast cells in vitro. Results of a radiolabeled tissue distribution study in rats and a radioligand *H_1-receptor* binding study in guinea pigs showed that desloratadine did not readily cross the blood brain barrier.

7-Pharmacokinetics:

Absorption: Following oral administration of desloratadine , the mean time to maximum plasma concentrations *(T_{max})* occurred at approximately 3 hours post dose. Food had no effect on the bioavailability *(AUC and C_{max})* of desloratadine Syrup.
Distribution: Desloratadine and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89%, bound to plasma proteins, respectively.
Metabolism: Desloratadine (a major metabolite of loratadine) is extensively metabolized to 3-hydroxydesloratadine, an active metabolite, which is subsequently glucuronidated.
Elimination: The mean elimination half-life of desloratadine was 27 hours which was equally distributed in urine and feces as metabolic products.

8-Indications:

Fernilar Syrup & Film coated tablet is indicated for the treatment of symptoms associated with Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis, Chronic Idiopathic Urticaria

9-Dosage & Administration:

Fernilar Tablet:
Adults and children 12 years of age and over:
5 mg film coated tablet once daily.
Fernilar Syrup:
Children 6 to 11 years of age:
The recommended dose of Fernilar syrup is 1 teaspoonful (2.5 mg in 5 mL) once daily.
Children 2 to 5 years of age:
The recommended dose of Fernilar syrup is ½ teaspoonful (1.25 mg in 2.5 mL) once daily.
The age-appropriate dose of Fernilar syrup should be administered with a commercially available measuring dropper or syringe that is calibrated to deliver 2.5 mL (½ teaspoonful).

10-Contraindications:

Fernilar is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to loratadine.

11-Side effects:

Headache, nausea, fatigue, dizziness, pharyngitis , dyspepsia, and myalgia and dry mouth.

12-Drug interactions:

There were no clinically relevant changes in the safety profile of desloratadine, as assessed by electrocardiographic parameters (including the corrected QT interval), clinical laboratory tests, vital signs, and adverse events.

13-Pregnancy & lactation:

Pregnancy category (C).
Desloratadine should not be used during pregnancy unless the benefit is clearly needed.
Desloratadine passes into breast milk so it must not be used during lactation.

14-Precautions & warning:

- Not to be used for children below 2 years of age.
- The safety and effectiveness of Desloratadine film coated tablets or Desloratadine syrup have not been demonstrated in pediatric patients less than 6 months of age.
Not used in renal insufficiency.
For Fernilar Syrup:
Due to presence of Sorbitol should not be used for diabetic patients.

15-Package & storage:

Fernilar Film coated tablets:
Store at a temperature not exceeding 30°C, in a dry place.
Carton Box containing two (AL/PVC) strips, each strip of 10 Film coated tablets with inner leaflet.
Fernilar Syrup:
Store at a temperature not exceeding 30°C
Carton box containing plastic (Polyethylene terphathalate) bottle of 60 ml with inner leaflet.

16-Instructions to patients:

- Patients should be instructed to use Fernilar as directed.
- As there is no food effects on bioavailability, patients can be instructed that Fernilar, may be taken without regard to meals.
- Patients should be advised not to increase the dose or dosing frequency, as studies have not demonstrated increased effectiveness at higher doses and somnolence may occur.

Manufactured by:
Egyptian Group For Pharmaceutical Industries.(EGPI)

EGPI

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