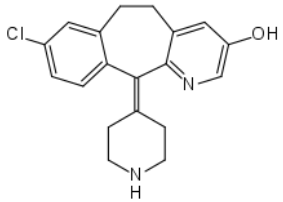
Name of the product: Beyond Tablets

Size of the insert (5x6.5 inch front & back printing)

# Beyond Tablets

# بی یونڈ ٹیبلٹس

**DESCRIPTION:**
The chemical name of Beyond (desloratadine) tablets is 8-chloro-6,11- dihydro-11-(4-piperdinylidene)-5H-benzo[5,6] cyclohepta[1,2-b]. Desloratadine has an empirical formula: C19H19ClN2 and a molecular weight of 310.8.




**COMPOSITION:**
Each film coated tablet contains: Desloratadine BP/USP.....5mg.

**INDICATIONS:**
Beyond (desloratadine) tablets are indicated for symptomatic relief of:
1. Allergic rhinitis (seasonal and perennial)
2. Chronic idiopathic urticaria

**INDICATIONS AND USAGE:**
***Allergic Rhinitis:*** Beyond Tablets 5 mg are indicated for the relief of the nasal and non-nasal symptoms of allergic rhinitis (seasonal and perennial) in patients 12 years of age and older.
***Chronic Idiopathic Urticaria:*** Beyond Tablets are indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria 12 years of age and older.

**CLINICAL PHARMACOLOGY**
***Mechanism of Action:*** Desloratadine is a long-acting tricyclic histamine antagonist with selective H1-receptor histamine antagonist activity. Desloratadine inhibits histamine release from human mast cells in vitro. It does not cross readily blood brain barrier.
***Absorption:***
Following oral administration of a desloratadine 5-mg tablet once daily for 10 days to normal healthy volunteers, the mean time to maximum plasma concentrations (Tmax) occurred at approximately 3 hours post dose and mean steady state peak plasma concentrations (Cmax) and AUC of 4 ng/mL and 56.9 ng.hr/mL were observed, respectively. Neither food nor grapefruit juice had an effect on the bioavailability (Cmax and AUC) of desloratadine
***Distribution:***
Desloratadine and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89%, bound to plasma proteins, respectively. Protein binding of desloratadine and 3-hydroxydesloratadine was unaltered in subjects with impaired renal function.
***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. Cmax and AUC values increased in a dose proportional manner following single oral doses between 5 and 20 mg. A human mass balance study documented a recovery of approximately 87% of the 14C-desloratadine dose, which was equally distributed in urine and feces as metabolic products.

**SPECIAL POPULATIONS**
***Renally Impaired patients:***
In patients with mild and moderate renal impairment, median Cmax and AUC values increased by approximately 1.2- and 1.9- fold, respectively, relative to subjects with normal renal function. In patients with severe renal impairment or who were hemodialysis dependent, Cmax and AUC values increased by approximately 1.7- and 2.5-fold, respectively.
***Hepatically Impaired patients:***
Patients with hepatic impairment, regardless of severity, had approximately a 2.4-fold increase in AUC as compared with normal subjects. The apparent oral clearance of desloratadine in patients with mild, moderate, and severe hepatic impairment was 37%, 36%, and 28% of that in normal subjects, respectively. An increase in the mean elimination half-life of desloratadine in patients with hepatic impairment was observed.
***Geriatric:***
In older subjects (≥ 65 years old) following multiple-dose administration of beyond Tablets, the mean Cmax and AUC values for desloratadine were 20% greater than in younger subjects (< 65 years old). The mean plasma elimination half-life of desloratadine was 33.7 hr in subjects ≥ 65 years old. These age-related differences are unlikely to be clinically relevant and no dosage adjustment is recommended in elderly subjects.

**CONTRAINDICATIONS:**
Beyond Tablets 5 mg are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to loratadine.

**TOXICITY:**
Information regarding desloratadine overdose is limited, although somnolence has been reported. In case of overdose, symptomatic and supportive treatment include removing the unabsorbed drug. Desloratadine and its active metabolite 3-hydroxydesloratadine cannot be eliminated by hemodialysis.

**ABUSE/ DEPENDENCE:**
No data is available to suggest that desloratadine causes abuse or dependence.

**PRECAUTIONS**
***Pediatric Use:***
Desloratadine has not been evaluated in patients less than 12 years of age.
***Geriatric Use:***
Dose might need to be reduced in case of concomitant disease/ other drug therapy, and greater likelihood of impaired hepatic, renal or cardiac function in these patients.

**USE IN PREGNANCY:**
- Desloratadine has been classified in pregnancy category c.
- Desloratadine does not cause teratogenicity even at very high doses like 60mg/kg/day.

Desloratadine tablet should be used during pregnancy only if clearly indicated since animal data is not necessarily suggestive of human response.
***Carcinogenicity, Mutagenicity 4 Fertility Impairment:***
In very high dosage of 700-2400 mg/day in animals. Desloratadine has been seen to cause impact on male fertility.
***Nursing mothers:***
Desloratadine passes into breast milk, therefore a decision should be made whether to discontinue nursing or to discontinue desloratadine, taking into account the importance of the drug to the mother.

**OVERDOSAGE**
- Limited information is available regarding over dosage of desloratadine at doses of 10 mg and 20 mg/day might cause somnolence
- At 45 mg single dose for 10 days, desloratadine might cause increase in heart rate of 9bpm.
- No clinically relevant adverse events were reported.
- Lethal dose has been estimated to be oral dose of 250 mg/kg or greater.
- Desloratadine and -hydroxydesloratidine are not hemodialysable.

**DRUG INTERACTIONS:**
When desloratadine is co-admisitrated with erythromycin, azithromycin, ketoconazole and fluoxetine, there is some increase in plasma concentrations of desloratadine and 3-hydroxydesloartidine.
**PRESENTATION:** Beyond tablets 5mg is available in packing containing 10 film coated tablets.
**STORAGE:** Avoid direct sunlight and protect from moisture and heat. Store below 25 °C. Keep away from the reach of children.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ دھوپ، نمی اور گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information only for doctors on request.

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Reference: FDA Label