Lotdis 5mg Tablets

Desloratidine

لوٹڈِس ۵ ملی گرام گولیاں

ڈیسلوراٹیڈین

COMPOSITION:
Each film coated tabled contains: Desloratadine 5 mg.
DESCRIPTION:
The Generic name of LOTDIS (Desloratadine) tablets is 8-chloro-6, 11-dihydro-11-(4-piperdinylidene)-5H-benzo(5.6 cyclohepta 1,2-bl pyridine.
Desloratadine has an empirical formula: $C_{19}H_{18}ClN_2$ and a molecular weight of 310.8.
INDICATIONS:
LOTDIS (desloratadine) tablets are indicated for symptomatic relief of
1. Allergic rhinitis (seasonal and pererinial)
2. Chronic idiopathic urticaria.
DOSAGE AND ADMINISTRATION:
Adults and children 12years and above:
- In individuals with normal hepatic and renal functions, the recommended dose of LOTDIS tablets is one tablet (5mg) once daily.
- n patients with hepatic and renal dysfunction, the dosing frequency is to be reduced to one 5mg LOTDIS tablet every two days.

Children under 12years of age:
Since use of desloratadine in adequate number of patients has not studied in this age group, LOTDIS tablets are not recommended in children under 12years of age.
MODE OF ACTION:
As a long-acting tricyclic histamine antagonist, desloratadine acts via selective H1-receptor histamine antagonist activity. Desloratadine inhibits Histamine release form human mast cells in vitro.
Desloratadine does not readily cross the blood brain barrier.
PHARAMACOKINETICS.
Absorption:
- In normal healthy indivduals, after oral administration of 5mg desloratidine once daily for 10 days, the mean time to maximum plasma concentration occurs at approximately 3 hours after dose.
- Mean steady peak concentration and area under the curve of 4 ng/ml and 56.9 ng.hr/ml are seen respectively, food has no affect on these levels.

Metabolism/Distribution:
- Desloratadine is extensively metabolized to active metabolite, 3-hydrturydeslorating which is later glucuronidated.
- Desloratadine and 3-hyroxydesloratadine are bound to plasma proteins 64% and 87% respectively.
- Impaired function does not any alteration in protein binding of desloratadine and 3-hydroxydesloratadine.

Elimination:
- Desloratadine has mean elimination hall-life of 27 hours.
- Following single 0ral doses between 5 and 20mg. C max and AUC values are dose related.
- The extent of drug accumulation is consistent with the half-life and dosing frequency after 14-day dosing. Approximately 87% of the desloratadine is excreted equally in urine and feces. Metabolite is also excreted in the same fashion.

Pharmacokinetics in Special Population Groups:
In hepatically impaired patients:
In hepatic Impairment, dosage adjustment has been recommended because of the following reasons.
- Regardless of severity, patients with hepatic impairment have approximately a 2.4-fold increase in AUG as compared with normal persons.
- Oral clearance of desloratadine in patients with mild, moderate, and severe hepatic impairment is 37%, 30% and 28% of that in normal subjects, respectively.
- In patients with hepatic impairment there is an increase in the mean elimination half-life of desloratadine.

In renally impaired patients:
In renal impairment, dosage adjustment has been recommended because of the following reasons.
- In mild to moderate impairment, C max and AUC values increase by approximately 1-2 1-0 Jold, respectively, as compared with C max and AUC values in normal renal function.
- In sever renal impairment and in hemodialysis dependent patient, C max and AUC values

- increase by approximately 1.7 and 2.5-fold, respectively

In old patients (>65)

There is no dosage adjustment recommendation is geriatric patients because the following age-differences are supposed be clinically Irrelevant to

- The mean C max and AUC values have been found to be 20% greater than in younger subjects following multiple dose administration of desloratine.
- In old age groug, the mean plasma elimination half the of desloratadine was observed to be 31.7 hours as compared with 27 hours in young individuals

CONTRAINDICATIONS: LOTOIS tablets are contraindicated in patients with known hypersensitivity to desloratadine of any of the ingredients.

TOXICITY OR SIDE EFFECTS:

- The incidence of adverse events is similar between desloratadine and placebo groups.
- The droport rates due to adverse events were also similar in both the proups (<3%).
- No serious adverse events were observed in patients receiving desioratadine.
- Side effects observed are mild to moderate and they are comparable to placebo in terms of incidence.

Desloratadine might cause the following side effects: pharyngitis, dry mouth, myalgia, fatigue, somnolence, and dysmenorrhea.

ABUSE/DEPENDENCE

No data is available to suggest that desoratadine causes abuse of dependence

PRECAUTIONS:

Pediatric Use:

Desloratadine has not been evaluated in patients less than 12 years of age

Geriatric use:

Dose of desloratadine in these patients might need to be reduced in case of concomitant disease other drug therapy and greater liklihood of impaired hepatic, renal or cardiac function in these patents.

Use in pregnancy:

- Desloratadine has been classified in pregnancy category C.
- Desloratadine does not cause teratogenicity seven at very high doses like 60mg/kg/day

LOTDIS tablets should be used during pregnancy only if clearly indicated since animal data is not necessarily suggestive of human response

Carcinogenicity, Mutagenicity & Fertility Impairment:

In very high dosage of 700-2400 mg/day in animals, desloratadine has been seen to cause impact ori male fertility.

Nursing mothers:

Since desloratadine is excreted into breast milk, physician should evaluate the benefit before prescribing LOTDIS tablets to nursing mothers.

Overdosage:

- Limited information is available regarding overdosage of desloratadine.
- At doses of 10-20mg/day desloratadine might cause somnolence.
- At 45mg single dose for 10 days, desloratadine might cause and increase in mean heart rate of 9bpm.
- No clinically relevant adverse events were reported.
- Lethal dose has been estimated to be at oral dose of 250 mg/kg (median lethal doseis353 mg/kg).
- In case of overdose, drug should be removed using standard procedures followed by symptomatic and supportive measures.
- Desloratadine and 3-hydroxydesloratadine are not hemodialysable.

DRUG INTERACTIONS:

When desloratadine is co-administered with erythromycin, azithromycin ketoconazole and floxentine, there is some increase in plasma concentrations of desloratadine and 3-hydrurydesloratadine

PRESENTATION:

LOTDIS 10mg tablet: 1x10 blister/pack.

PRECAUTION:

- Use as prescribed by the physician.
- Keep out of the reach of children.
- Store at room temperature.
- Protect from direct sunlight, heat & moisture.

ہدایات:

دواڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

بچوں کی پہنچ سے دور رکھیں۔

کمرے کے درجہ حرارت پر رکھیں۔

سورج کی روشنی، گرمی اور نمی سے محفوظ رکھیں۔

Manufactured by:
Aims Pharmaceuticals
Plot # 291, Industrial Triangle
Kahuta Road, Islamabad - Pakistan.
www.aimspharmaceuticals.com