DOARA ڈورا

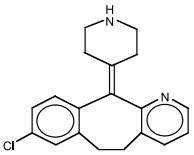
(D e s l o r a t a d i n e)

5mg Tablets

DESCRIPTION

DOARA (Desloratadine) is a non-sedating long acting histamine antagonist with selective peripheral H_1-receptor antagonist activity.

Chemically, desloratadine is 8-chloro-6, 11-dihydro-11-(4-piperdinylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine. The molecular formula is $C_{19}H_{19}ClN_2$ and the structural formula is:



Desloratadine

QUALITATIVE AND QUANTITATIVE COMPOSITION

DOARA (Desloratadine) is available for oral administration as:

DOARA Tablets 5mg
Each film coated tablet contains:
Desloratadine … 5mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Desloratadine is a long-acting tricyclic histamine antagonist with selective H_1-receptor histamine antagonist activity. Receptor binding data indicates that at a concentration of 2-3ng/mL, desloratadine shows significant interaction with the human histamine H_1-receptor. Desloratadine inhibited histamine release from human mast cells *in-vitro*.

Pharmacokinetics

Absorption

Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours. The area under the concentration time curve (AUC) is 56.9ng.hr/ml and the mean steady state peak plasma concentrations (C_{max}) is 4ng/ml. The bioavailability of desloratadine was dose proportional over the range of 5mg to 20mg.

Metabolism

Desloratadine is extensively metabolized to 3-hydroxydesloratadine an active metabolite, which is subsequently glucorinated.

Distribution

Desloratadine and 3-hydroxydesloratadine are approximately 82% to 87% and 85% to 89% bound to plasma proteins.

Excretion

The mean elimination half-life of desloratadine was 27 hours. The degree of accumulation after 14 days of dosing was consistent with the half-life and dosing frequency.

Special Populations

Renal Impairment

In patients with mild and moderate renal impairment, median C_{max} 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, C_{max} and AUC values increased by approximately 1.7- and 2.5- fold, respectively. Desloratadine and 3-hydroxydesloratadine were poorly removed by hemodialysis. Dosage adjustment for patients with renal impairment is recommended.

Hepatic Impairment

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. Dosage adjustment for patients with hepatic impairment is recommended.

THERAPEUTIC INDICATIONS

- **Seasonal allergic rhinitis**
  DOARA (Desloratadine) tablets are indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 12 years of age or older.
- **Perennial allergic rhinitis**
  DOARA (Desloratadine) tablets are indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 12 years of age or older.
- **Chronic idiopathic urticaria**
  DOARA (Desloratadine) tablets are indicated for the symptomatic relief of pruritis, reduction in the number of hives, in patients with chronic idiopathic urticaria 12 years of age and older.

DOSAGE AND ADMINISTRATION

The recommended dose of **DOARA** (Desloratadine) tablets is one 5mg tablet once daily with or without a meal.

Patients with renal and hepatic impairment:

In patients with renal or hepatic impairment, a starting dose of one 5mg tablet every other day is recommended based on pharmacokinetic data.

Pediatric use:

DOARA (Desloratadine) tablets are not indicated for children under 12 years of age.

ADVERSE REACTIONS

Generally desloratadine is well tolerated. The most common side effects reported during therapy with desloratadine were fatigue, headache and dry mouth. Other adverse effects reported very rarely were: Hallucinations, dizziness, somnolence, insomnia, psychomotor, hyperactivity, seizures, tachycardia, palpitations, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, elevations of liver enzymes, increased bilirubin, hepatitis, myalgia, hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticaria).

CONTRAINDICATIONS

Desloratadine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to desloratadine, to loratadine or to any of the excipients.

PRECAUTIONS

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pregnancy

There are no adequate and well-controlled studies of desloratadine in pregnant women. Desloratadine should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Nursing Mothers

Desloratadine passes into human breast milk; therefore, a decision should be made whether to discontinue desloratadine, taking into account the importance of the drug to the mother.

DRUG INTERACTIONS

No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered.

OVERDOSAGE

In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.

STORAGE

Store at 25°C (Excursions permitted between 15°C to 30°C).
Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

DOARA (Desloratadine) Tablets 5mg are available in blister pack of 10's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

ہدایات:

دوا کو ۲۵ ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں۔
(درجہ حرارت کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے)۔
دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

SCILIFE
Manufactured by:
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