D-NEXT™

(As per Innovator's Specification)

Desloratadine

(USP Specification)

5mg Film Coated Tablets & **0.5**mg/ml Syrup

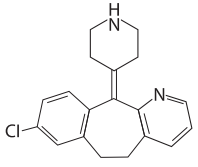
COMPOSITION

D-NEXT (Desloratadine) is available for oral administration as:
D-NEXT Tablets 5mg Each film-coated tablet contains:
Desloratadine 5mg
(As per Innovator's Specification)
D-NEXT Syrup 120ml Each ml contains:
Desloratadine 0.5mg
(As per Innovator's Specification)

DESCRIPTION

D-NEXT (Desloratadine) is a non-sedating long acting histamine antagonist with potent, selective peripheral H1-receptor antagonist activity. Chemically, desloratadine is 8-chloro-6, 11-dihyrdo- 11-(4-piper-dinylidene)- 5H benzo[5,6]cyclohepta[1,2-ID]pyridine. The molecular formula is 091-119CIN2 and the structural formula is:

Desloratadine



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.

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 Population

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—and AUC values increased by approximately 1.7- and 2.50 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:

D-NEXT (Desloratadine) tablets/syrup 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 :

D-NEXT (Desloratadine) tablets/syrup 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:

D-NEXT (Desloratadine) tablets/syrup are indicated for the symptomatic relief of pruritus, reduction in the number of hives, in patients with chronic idiopathic urticaria 12 years of age or older.

DOSAGE AND ADMINISTRATION

D-NEXT (Desloratadine) may be taken with or without food or on a full or empty stomach. However, if your doctor tells you to take the medicine in a certain way, take it exactly as directed. The dose of desloratadine may be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of desloratadine. If your dose is different, do not change

it unless your doctor tells you to do so.

Adults and children 12 years of age and over: The recommended dose is one 5mg tablet or 2 teaspoonful syrup (5mg in 10ml) once daily.

Children 6 to 11 years of age: The recommended dose is 1 teaspoonful syrup (2.5mg in 5ml) once daily.

Children 12 months to 5 years of age: The recommended dose is 1/2 teaspoon (1.25mg in 2.5ml) once daily

Children 6 to 11 months of age: The recommended dose is 2ml syrup (1.0mg) once daily.

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.

ADVERSE REACTIONS

Generally desloratadine is well tolerated. The most common side effects are fatigue, headache and dry mouth. Other adverse effects reported very rarely were: Dizziness, somnolence, insomnia, 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 utricaria).

CONTRAINDICATIONS

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

PRECAUTIONS

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.

STORAGE

D-NEXT (Desloratadine) 5 mg Tablets:
Store at 20°C - 25°C. Protect from light and moisture.
(excursions permitted to 15°C - 30°C).
D-NEXT (Desloratadine) 0.5 mg / ml Syrup:
Store below 30°C . Protect from light.

HOW SUPPLIED

D-NEXT (Desloratadine) Tablet 5mg is available in alu alu pack of 1 x 10's.
D-NEXT (Desloratadine) Syrup 0.5mg/m1 is available in 120ml bottle.

Keep medicines out of the reach of children.

Lactose & Gluten Free

ڈی- نیکسٹ
(ڈیسلوراٹاڈین)

5 ملی گرام فلم کوٹڈ گولیاں

خوراک وہدایات

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 25°C-20°C درجہ حرارت پر نمی اور روشنی سے محفوظ رکھیں۔

(درجہ حرارت کی حد 15°C سے 30°C ہے)

0.5 ملی گرام/ملی لیٹر سیرپ

خوراک وہدایات:

12 سال یا اس سے زیادہ عمر کے بالغ اور نوعمر افراد کیلئے:

10 ملی لیٹر روزانہ ایک بار لیا جائے۔

6-11 سال کی عمر کے بچوں کیلئے: 5 ملی لیٹر روزانہ ایک بار لیا جائے۔

12 ماہ سے 5 سال کی عمر کے بچوں کیلئے: 2.5 ملی لیٹر روزانہ ایک بار لیا جائے۔

6-11 ماہ کی عمر کے بچوں کیلئے: 2 ملی لیٹر روزانہ ایک بار لیا جائے۔

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔ صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

30°C سے کم درجہ حرارت پر روشنی سے محفوظ رکھیں۔

NEXT PHARMACEUTICAL
Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
Plot no. 44-A&B, Sunder Industrial Estate Lahore-Pakistan