120mm

120mm

181mm

Syrup / Tablet

NEULORAX

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

نیولوریکس سیرپ/ٹیبلیٹ

(ڈیسلوریٹاڈائین)

COMPOSITION:

Neulorax Tablet 5mg

Each film coated tablet contains:

Desloratadine 5mg

(USP Specification)

Neulorax Syrup 0.5mg/ml

Each ml contains:

Desloratadine 0.5mg

(Innovator's Specification)

DESCRIPTION:

Neulorax (Desloratadine) is a non-sedating long acting histamine antagonist with potent, selective peripheral H1- receptor antagonist activity.

Mechanism of Action

Desloratadine is a selective H1-antihistamine which functions as an inverse agonist at the histamine H1 receptor it is also an antagonist at all subtypes of the muscarinic acetylcholine receptors. It inhibits histamine release from human mast cells. It has a long-lasting effect and in moderate and low doses. It exhibits only peripheral activity since it does not readily cross the blood-brain barrier hence, it does not cause drowsiness because it does not readily enter the central nervous system.Like other H1-blockers, Desloratadine competes with free histamine for binding at H1-receptors in the GI tract, uterus, large blood vessels, and bronchial smooth muscle. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms (e.g. nasal congestion, watery eyes) brought on by histamine.

THERAPEUTIC INDICATIONS:

- **Seasonal Allergic Rhinitis**

Neulorax (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**

Neulorax (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**

Neulorax (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 & ADMINISTRATION:

NEULORAX syrup / tablet may be taken with or without food or on a full or empty stomach.

For Syrup:

Adults and children 12 Years of Age and over

The recommended dose of NEULORAX syrup is 2 teaspoonful (5 mg in 10 mL) once daily.

Children 6 To 11 Years of Age

The recommended dose of NEULORAX syrup is 1 teaspoonful (2.5 mg in 5 mL) once daily.

Children 12 Months to 5 Years of Age

The recommended dose of NEULORAX syrup is ½ teaspoonful (1.25 mg in 2.5 mL) once daily.

Children 6 To 11 Months of Age

The recommended dose of NEULORAX syrup is 2 mL (1 mg) once daily.

For Tablet:

Adults & adolescents 12 years and over

One tablet (5mg) daily.

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 (Cmax) 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.

PRECAUTIONS:

Hypersensitivity reactions including rash, pruritus, urticaria, edema, dyspnea, and anaphylaxis have been reported after administration of desloratadine. If such a reaction occurs, therapy with NEULORAX should be stopped and alternative treatment should be considered.

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, desloratadine should be used during pregnancy only if clearly needed.

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 benefit of the drug to the nursing mother and the possible risk to the child.

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, dyspnea, pruritus, rash and urticaria).

DRUG INTERACTIONS:

- **Inhibitors of Cytochrome P450 3A4**

In controlled clinical studies co-administration of desloratadine with ketoconazole, erythromycin, or azithromycin resulted in increased plasma concentrations of desloratadine and 3 hydroxydesloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.

- **Fluoxetine**

In controlled clinical studies co-administration of desloratadine with fluoxetine, a selective serotonin reuptake inhibitor (SSRI), resulted in increased plasma concentrations of desloratadine and 3 hydroxydesloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.

- **Cimetidine**

In controlled clinical studies co-administration of desloratadine with cimetidine, a histamine H2-receptor antagonist, resulted in increased plasma concentrations of desloratadine and 3 hydroxydesloratadine, but there were no clinically relevant changes in the safety profile of desloratadine.

CONTRAINDICATIONS:

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

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight & moisture.

Keep away from the reach of children.

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

HOW SUPPLIED:

Neulorax Tablet 5mg.

10's, 10x10's Tablets.

Neulorax Syrup 0.5mg/ml.

60ml, 120ml bottle.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.