

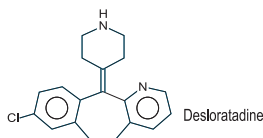
210mm

Neo-Antial[®] Tablets / Syrup

(Desloratadine)

DESCRIPTION:

It has an empirical formula: C₁₉H₁₉ClN₂ and a molecular weight of 310.8. The chemical name is 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine and has the following structure:



COMPOSITION:

Neo-Antial 5mg Tablets

Each film coated tablet contains:

Desloratadine MS,5mg

Neo-Antial 0.5mg/ml Syrup

Each ml of syrup contains:

Desloratadine MS..... 0.5mg

CLINICAL PHARMACOLOGY:

Mechanism of Action:

Desloratadine is a long-acting tricyclic histamine antagonist with selective H₁-receptor histamine antagonist activity

PHARMACOKINETICS:

Absorption:

Following oral administration of desloratadine 5mg once daily for 10 days to normal healthy volunteers, the mean time to maximum plasma concentrations (T_{max}) occurred at approximately 3 hours post dose and mean steady state peak plasma concentrations (C_{max}) and area under the concentration-time curve (AUC) of 4ng/ml and 56.9ng.hr/ml were observed, respectively. Neither food nor grapefruit juice had an effect on the bioavailability (C_{max} 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. The enzymes responsible for the formation of 3-hydroxydesloratadine have not been identified

Elimination:

The mean elimination half-life of desloratadine is 27 hours. C_{max} and AUC values increased in a dose proportional manner following single oral doses between 5 and 20mg. The degree of accumulation after 14 days of dosing was consistent with the half-life and dosing frequency

Pharmacodynamics:

Human histamine skin wheal studies following single and repeated 5mg doses of desloratadine have shown that the drug exhibits an antihistaminic effect by 1 hour; this activity may persist for as long as 24 hours

INDICATIONS AND USAGE:

Seasonal Allergic Rhinitis:

Neo-Antial is indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 2 years of age and older

Perennial Allergic Rhinitis:

Neo-Antial is indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 6 months of age and older

Chronic Idiopathic Urticaria:

Neo-Antial is indicated for the symptomatic relief of pruritus, reduction in the number of hives and size of hives in patients with chronic idiopathic urticaria 6 months of age and older

CONTRAINDICATIONS:

Neo-Antial is contraindicated in patients who are hypersensitive to this medication or to any of its ingredients or to loratadine

PRECAUTIONS:

Pregnancy Category C:

There are no adequate and well-controlled studies in pregnant women

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

Paediatric Use:

The safety and effectiveness of **Neo-Antial** tablets or **Neo-Antial** syrup have not been demonstrated in paediatric patients less than 6 months of age

Adverse Reactions: The common adverse events are pharyngitis, dry mouth, myalgia, fatigue, somnolence and dysmenorrhea

120mm

210mm

DOSAGE AND ADMINISTRATION:

Adults and children 12 years of age and over:

The recommended dose of **Neo-Antial** tablets is one 5mg tablet once daily or the recommended dose of **Neo-Antial** syrup is 2 teaspoonfuls (5mg in 10ml) once daily

Children 6 to 11 years of age:

The recommended dose of **Neo-Antial** syrup is 1 teaspoonful (2.5mg in 5ml) once daily

Children 12 months to 5 years of age: The recommended dose of **Neo-Antial** syrup is 1/2 teaspoonful (1.25mg in 2.5ml) once daily

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

The age-appropriate dose of **Neo-Antial** syrup should be administered with a commercially available measuring dropper or syringe that is calibrated to deliver 2ml and 2.5ml (1/2 teaspoonful)

Adult patients with Hepatic or renal impairment: A starting dose of one 5mg tablet every other day is recommended

OR

As directed by the physician

PRESENTATION:

Neo-Antial 5mg tablets in a pack of 10's

Neo-Antial syrup in a pack of 60ml

STABILITY:

See expiry on the pack

INSTRUCTIONS:

Keep out of reach of children

Avoid exposure to heat, light, humidity and freezing

Store between 15 to 30°C

Improper storage may deteriorate the medicine

Caution: Medicine should not be used if container is leaking or it contains un-dissolved particle(s)

نیو-انٹیل (ڈیس لورائٹا ڈین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی، نمی اور نمند ہونے سے محفوظ رکھیں ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: دوا کے لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل پذیر شے نظر

آنے کی صورت میں ہرگز استعمال نہ کریں



Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.J.T.E., Karachi-Pakistan
www.samipharmapk.com

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R.N-08/HA/05/16/Pampac/Tabss.

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