Antial®
Tablets / Oral Solution
(Loratadine)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Antial® 10mg Tablets
Each tablet contains:
Loratadine USP.....10mg

Antial® Oral Solution
Each 5ml contains:
Loratadine USP.....5mg

PHARMACEUTICAL FORM
Tablet / Oral Solution

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS:
Antial® is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and children over the age of 2 years.

POSOLOGY AND METHOD OF ADMINISTRATION:
POSOLOGY:
Adults and children over 12 years of age: 10mg tablet once daily. The tablet may be taken without regard to meal time OR 10ml (10mg) of the oral solution once daily.

Paediatric population:
Children 2 to 12 years of age are dosed by weight:
Body weight more than 30kg: 10mg tablet once daily OR 10ml (10mg) of the oral solution once daily.

Body weight 30kg or less: 5ml (5mg) of the oral solution once daily. Tablets are not suitable in children with a body weight less than 30kg.

Efficacy and safety of loratadine in children under 2 years of age has not been established.

Patients with severe liver impairment: Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine.

An initial dose of 10mg every other day is recommended for adults and children weighing more than 30kg, and for children weighing 30kg or less, 5ml (5mg) every other day is recommended.

Patients with severe renal impairment: No dosage adjustments are required in the elderly or in patients with renal insufficiency.

Elderly: No dosage adjustments are required in the elderly.

Method of administration: For oral administration.

CONTRAINDICATIONS:
Antial® is contraindicated in patients who have shown sensitivity to loratadine.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
- Should be administered with caution in patients with severe liver impairment
- This medicinal product contains sucrose; patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- The administration of loratadine should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
- When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.
- Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine, which may cause an increase in adverse events.
- Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).

Paediatric population: Interaction studies have only been performed in adults.

FERTILITY, PREGNANCY AND LACTATION:
Fertility: There are no data available on male and female fertility.

Pregnancy: A large amount of data on pregnant women indicate no malformative nor foeto/neonatal toxicity of loratadine. As a precautionary measure, it is preferable to avoid the use during pregnancy.

Breast-feeding: Loratadine is excreted in breast milk, therefore use is not recommended in breast-feeding women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
In known clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

UNDESIRABLE EFFECTS:

System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Very rare	Hypersensitivity reactions(including angioedema and anaphylaxis)
Nervous system disorders	Very rare	Dizziness, convulsion
Cardiac disorders	Very rare	Tachycardia, palpitation
Gastrointestinal disorders	Very rare	Nausea, dry mouth, gastritis
Hepato-biliary disorders	Very rare	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Very rare	Rash, alopecia
General disorders and administration site conditions	Very rare	Fatigue

In known clinical trials involving adults and adolescents in a range of indications including AR and CIU, at the recommended dose of 10mg daily, adverse reactions with loratadine were known to be reported in 2% of patients in excess of those treated with the placebo. The most frequent adverse reactions known to occur in excess of placebo were:
- Somnolence (1.2%)
- Headache (0.6%)
- Increased appetite (0.5%)
- Insomnia (0.1%)

Paediatric population: In known clinical trials in a paediatric population children aged 2 through 12 years, common adverse reactions known to be reported in excess of placebo were:
- Headache (2.7%)
- Nervousness (2.3%)
- Fatigue (1%)

OVERDOSE:
Over dosage with loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses. In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Anti histamines – H_1 antagonist, **ATC code:** R06A X13.

Mechanism of action: Loratadine is a tricyclic antihistamine with selective, peripheral H_1-receptor activity.

Pharmacodynamic effects:
No clinically significant sedative or anticholinergic properties are known to occur in the majority of the population and when used at the recommended dosage. Loratadine has no significant H_2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

PHARMACOKINETIC PROPERTIES:
Absorption: Loratadine is rapidly and well-absorbed. Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect. The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

Distribution: Loratadine is highly bound (97% to 99%) and its active major metabolite desloratadine (DL) moderately bound (73% to 76%) to plasma proteins. In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours respectively.

Biotransformation: After oral administration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite desloratadine (DL) is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve maximum plasma concentrations (Tmax) between 1–1.5 hours and 1.5–3.7 hours after administration, respectively.

Elimination: Approximately 40% of the dose is excreted in the urine and 42% in the faeces over a 10-day period and mainly in the form of conjugated metabolites. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Less than 1% of the active substance is excreted unchanged in the active form, as loratadine or DL.

Renal impairment: The mean elimination half-lives of loratadine and its active metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

Hepatic impairment: In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (C_{max}) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Elderly: The pharmacokinetic profile of loratadine and its active metabolite is comparable in healthy adult volunteers and in healthy geriatric volunteers.

SHELF LIFE
See expiry on the pack.

AVAILABILITY
Antial® 10mg tablets in a pack of 20's
Antial® oral solution in a pack of 30ml

INSTRUCTIONS
Dosage: As advised by the physician.
To be sold on the prescription of registered medical practitioner only.
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.

Medicine should not be used if container is leaking
or it contains undissolved particle(s).

انٹیال ٹیبلٹ/اورل سلوشن
(لوراٹاڈین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو گرمی، روشنی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰
ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

دوا کے ایک ہونے یا اس میں کوئی غیر حل
پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

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