This package insert is continually updated: Please read carefully before using a new pack

Loratadine Tablets I.P. 10mg

Avil® advance

COMPOSITION

Each uncoated tablet contains:
Loratadine I.P. …….10mg
Excipients…… .q.s.

INDICATIONS

Long acting anti histaminic- In treatment of allergic rhinitis, acute coryza, chronic idiopathic urticaria.

DOSAGE AND ADMINISTRATION

Adults: One tablet once daily.

Paediatric population:

Children 6 years of age and older with a body weight greater than 30 kg: One tablet once daily. Dosage should be carefully evaluated for children of 6 years of age and older and to be administered under supervision.

For children younger than 6 years or with body weight of 30 kg or less, Avil® advance is not recommended.

Patients with hepatic impairment:
Patients with severe liver impairment have reduced clearance of loratadine. Hence, an initial dose of 10 mg every other day is recommended for adults and children weighing more than 30 kg.

Patients with renal impairment:
No dosage adjustments are required in patients with renal insufficiency.

Elderly:
No dosage adjustments are required in the elderly.

CONTRAINDICATIONS

Avil® advance is contraindicated in patients who are hypersensitive to this drug, including its metabolite, Desloratadine or to any ingredient in the formulation.

WARNINGS AND PRECAUTIONS

- Dosing adjustment is recommended in patients with severe liver disease. Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. (see dosage and administration)

- No dosage adjustments are required in patients with renal insufficiency. In the case of severe renal insufficiency, loratadine should be used with caution.

PREGNANCY & LACTATION

Pregnancy:
A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor feto / neonatal toxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Thus, this drug may be used during pregnancy only if the benefit outweighs the risk to the fetus. As a precautionary measure, it is preferable to avoid the use of Avil® advance during pregnancy.

Lactation:
Loratadine is excreted in breast milk. Therefore, the use of Avil® advance is not recommended in breast-feeding women.

DRUG INTERACTIONS

- When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

- Increases in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic). Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

- Loratadine should be discontinued approximately 48 hours prior to skin tests since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

- 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.

- Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect.

ADVERSE REACTIONS

Adverse experiences reported with loratidine in adults during clinical trials were mild and consisted of fatigue, headache, dry mouth, sedation, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash.

Nervousness and hyperkinesia were among the reported adverse experiences in pediatric patients. Gastrointestinal adverse reactions reported during pediatric trials may have been slightly more frequent in the younger patients (less than or equal to 30 kg).

During the marketing of loratadine, alopecia, anaphylaxis, abnormal hepatic function, dizziness, palpitations and tachycardia have been rarely reported.

DRIVING AND/OR OPERATING HEAVY MACHINARY OR PERFORMING OTHER HAZARDOUS TASKS

In clinical studies that assessed driving ability, no impairment was observed in patients receiving loratadine. Avil® advance has no or negligible influence on the ability to drive and use machines. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

OVERDOSAGE

Overdosage 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.

PRESENTATION:

- A blister of 5 Tablets
- 20 blisters of 5 Tablets per carton

STORAGE INSTRUCTIONS: Store below 30°C. Protect from moisture. Keep out of reach of children.

Manufactured in India by: Windlas Biotech Private Limited, (Plant-2), Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110, Uttarakhand (India)

Marketed by: Sanofi India Limited, (Sanofi Consumer Healthcare), Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

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Reference:

1. Product monograph of CLARITIN® ALLERGY (Loratadine Tablets USP 10 mg) by Bayer Inc, last updated on May 16th, 2019
2. Summary of Product Characteristics of Clarityn Allergy 10mg Tablets (GSL) by Bayer plc last updated on 17-Oct-2019