

Abridged Prescribing Information

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: For patients with severe liver impairment, 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.

SAFETY RELATED INFORMATION

Contraindications: Patients who are hypersensitive to this drug, including its metabolite, Desloratadine or to any ingredient in the formulation.

Precautions and Warnings: Patients with severe liver impairment should be administered a lower initial dose (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: It is preferable to avoid the use of Avil® advance during pregnancy and lactation.

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 reported rarely.

For full prescribing information, please contact: Sanofi India Limited, (Sanofi Consumer Healthcare), Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

Created: May 2020

Source: PI of Avil® advance (May 2020)