

# Lora<sup>®</sup>

Loratadine USP

**Description:** Loratadine (Lora<sup>®</sup>) is a non-sedative H<sub>1</sub> receptor antagonist with antiallergic properties, devoid of anticholinergic activity. It is rapidly effective and long lasting antihistamine.

**Mode of action:** Loratadine (Lora<sup>®</sup>) competitively antagonizes histamine at the H<sub>1</sub> receptor site.

**Pharmacokinetics:** Loratadine (Lora<sup>®</sup>) is widely absorbed (>90%) after oral administration. Mean plasma half-life is 12±4 hours. There was no evidence of toxicity after administration of a maximal dose of 160 mg (single dose) or 40 mg twice daily for 28 days (multiple dose). The effect begins within 1-3 hours, reaches a maximum at 8-12 hours, and lasts for more than 24 hours. Loratadine (Lora<sup>®</sup>) is extensively and rapidly metabolized in the liver. Following a single oral administration of 40 mg, 27% of the dose is eliminated in the urine within the first 24 hours and over a 10 day period about 40% is excreted in the urine and 42% in the faeces.

## Composition

**Lora<sup>®</sup> 10 mg Tablet:** Each tablet contains Loratadine USP 10 mg.

**Lora<sup>®</sup> Suspension:** Each 5 ml contains Loratadine USP 5 mg.

**Indications:** Seasonal allergic rhinitis, perennial allergic rhinitis, skin allergies including chronic urticaria.

**Dosage & administration:** Adults and children over 30 kg of body weight: 10 mg once daily, children under 30 kg or under 5 years of age: 5 mg once daily, children under 2 years: not recommended.

**Contraindications:** Hypersensitivity or idiosyncrasy to any component of Loratadine.

**Side effects:** Side effects of loratadine are generally mild. Fatigue, dizziness, dry mouth, headache, sedation, nausea and pruritus may be reported.

**Use in pregnancy & lactation:** US FDA pregnancy category C. Loratadine is excreted in the breast milk. So, it is not indicated to lactating mother.

**Precautions:** Severe hepatic impairment alters the pharmacokinetics of Loratadine and dose adjustment is required. Caution should be exercised when driving a car or operating potentially dangerous machinery.

**Drug interactions:** Concomitant use with Ketoconazole, Cimetidine, Nifedipine or Erythromycin may increase the plasma concentration of Loratadine.

**Overdosage:** There is little information on acute overdosage. Nausea, vomiting, hypotension, tachycardia, ataxia, and drowsiness have been reported.

**Storage:** Store in a cool and dry place, protected from light.

## Packaging

**Lora<sup>®</sup> 10 mg Tablet:** Each carton contains 10X10 tablets in blister pack.

**Lora<sup>®</sup> Suspension:** Each carton contains a bottle having 60 ml suspension.