

MODULE 1	:	ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION	Revision: MAY/16/00
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For registration :: Myanmar, Vietnam, Cambodia, Nigeria, Yemen, Sri Lanka, Kenya, Uganda,
Tanzania, Uzbekistan, Russia, Kazakhstan
Artwork of insert "Loreze" for Auto machine Code : RI-L076-M10-00-00
Size : 132 x 186 mm

<p>(Front)</p> <div style="border: 1px solid black; padding: 10px;"> <p>LOREZE (Capsule)</p> <p>Composition Each softgel capsule contains: Loratadine Hydrochloride 10 mg</p> <p>Other ingredients: Polyethylene glycol 400, propylene glycol, polyorbital, gelatin, glycerin, brilliant blue, purified water</p> <p>Pharmacodynamics Loratadine is a long acting antihistamine. The drug has been characterized as a specific, selective peripheral H₁-receptor antagonist and has been referred to as a second generation antihistamine.</p> <p>Pharmacokinetics Loratadine is rapidly absorbed from the GI tract following oral administration. Following oral administration of a single 10 mg dose of loratadine in healthy adults, mean peak plasma concentrations of 4.7 and 4.1 ng/ml of the drug and its active metabolite desloratadine were attained in about 1.5 and 2.5 hours, respectively. Following oral administration of loratadine, the antihistaminic effect of the drug is apparent within 1-4 hours, and the onset of antihistaminic action appears to correlate with absorption of loratadine and formation of desloratadine.</p> <p>Distribution of loratadine and its metabolites into human body tissues and fluids has not been determined. Large plasma volume following oral administration of loratadine suggest extensive presystemic metabolism and/or tissue distribution of the drug in humans.</p> <p>The mean distribution half-life of unchanged loratadine was about 1-2 hours, and the mean elimination half-life was 8-10 hours; the mean distribution half-life of desloratadine was 2-4 hours, and the mean elimination half-life was about 17-20 hours. Plasma clearance of loratadine is high after oral administration, probably secondary to extensive first-pass metabolism and tissue distribution. Loratadine undergoes extensive first-pass metabolism, and is metabolized in the liver by the cytochrome P-450 (CYP) microsomal enzyme system, principally by hydrolysis of the carbamate moiety to the active metabolite desloratadine.</p> <p>After 10 days of daily administration of loratadine, about 80% of the drug is excreted as metabolic products equally excreted in urine and feces.</p> <p>Product Specification - Manufacturer</p> <p>Indications</p> <ul style="list-style-type: none"> Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> Rhinitis (runny nose) Sneezing Itchy, watery eyes Itching of the nose or throat Symptomatic relief of pruritus, erythema, and urticaria associated with chronic idiopathic urticaria. <p>Dosage : Adults and children 6 years of age and older : 1 capsule once daily or as directed by a physician.</p> <p>Mode of Administration : (Oral Administration)</p> <p>Warnings / Precautions Patients with hepatic impairment or renal insufficiency (e.g. glomerular filtration rate less than 30 mL/minute), including geriatric patients, have decreased clearance of the drug, and should be given a lower initial dose of loratadine. Patients should be advised to discontinue loratadine therapy immediately and to contact their doctor if any signs of an allergic reaction occur.</p> <p>Contraindications Hypersensitivity or intolerance to any component of the product.</p> <p>Drug Interactions Although increased plasma concentrations of loratadine and its active metabolite desloratadine have been reported when the drug was concomitantly administered with therapeutic dosages of tetracycline, erythromycin, clarithromycin, or zalcitabine in controlled clinical pharmacology studies in healthy individuals, no clinically important changes in pharmacokinetic or laboratory parameters, vital signs, or adverse effects were reported.</p> </div>	<p>31 mm</p>	<p>(Back)</p> <div style="border: 1px solid black; padding: 10px;"> <p>Pregnancy & Lactation Because there are no adequate and controlled studies to date using loratadine in pregnant women, loratadine should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. Loratadine and desloratadine distributed readily into breast milk, achieving concentrations that are equivalent to those in plasma. Caution should be exercised when loratadine is administered to a nursing woman.</p> <p>Effects on ability to drive and use machines Loratadine has influence on ability to drive and use machines. Sedation (e.g. drowsiness, fatigue) occurred in about 12% (n = 8) and 4% (n = 4) respectively of patients receiving loratadine in clinical trials. The incidence of drowsiness appears to be dose related, although the incidence of drowsiness in patients receiving 10 mg of loratadine was greater than that of patients receiving placebo. Dose-related drowsiness becomes more prominent with doses of 20-40 mg.</p> <p>Side Effects The most frequent adverse effects reported with loratadine are nervous system effects. Adverse nervous system effects occurring in patients at usual doses receiving loratadine in clinical trials include: Epileptiform, dizziness, drowsiness, ataxia, hypotonia, migraine, paraesthesia, vertigo, vertigo, agitation, anxiety, ataxia, confusion, decreased libido, depression, impaired concentration, irritability, mixed dreaming, headache and sedation.</p> <p>Overdose & Treatment The acute lethal dose of loratadine in humans is not known. In adults, drowsiness, tachycardia, and headache have been reported after overdoses (e.g. 40-180 mg) of loratadine tablets. Treatment of loratadine overdose generally involves symptomatic and supportive care, initiated promptly and maintained as long as necessary. In acute loratadine overdosage, the stomach should be emptied immediately by inducing emesis with ipecac syrup. Administration of activated charcoal after emesis may be useful in promoting absorption of loratadine.</p> <p>Storage : Store below 25°C in a dry place, away from direct sunlight.</p> <p>Packaging Unit cartons containing 3 x 10 capsules blister pack.</p> <p>Notes - Read the instructions carefully before use. - Do not use the product after the expiry date. - Do not use the product if there are significant changes in appearance of the capsules. - Keep out of reach of children.</p> <p>Manufactured under license from: MEGA LIFESCIENCES (AUSTRALIA) PTY. LTD. 610 National Avenue, Dandenong, Victoria 3010, Australia</p> <p>By MEGA LIFESCIENCES Public Company Limited 254, Pattana 2 Rd., Bangsoo Industrial Estate, Bangkok 10080, Thailand</p> <p>Special date:</p> <p style="text-align: right;">RI-L076-M10-00-00</p> </div>
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Spelling checked by :

Date :

Approved by : (RA Director)

Date :