



**MEDLEY PHARMACEUTICALS**

## **Loramed** Syrup and Tablets

### **Loratadine USP**

#### **DESCRIPTION:**

Each 5 ml of Loramed syrup contains 5 mg of micronized Loratadine, whereas each Tablet of Loramed contains 10mg of micronized Loratadine, which is a potent long acting tricyclic azatadine derivative antihistamine with selective peripheral H1 receptor antagonistic activity. Chemical name of Loratadine is 1-Pipridinecarboxylic acid, 4-(8-chloro- 5,6-dihydro-11 *H*- benzo[5,6] cyclohepta [1,2-*b*] pyridine-11-ylidene)-1-piperidine carboxylate, while the empirical formula is C<sub>22</sub>H<sub>23</sub>ClN<sub>2</sub>O<sub>2</sub>.

#### **PHARMACOKINETICS:**

Loramed (Loratadine) after single or multiple oral administration, absorbed rapidly from GIT and in most of the patients, it attains peak plasma concentration in about 1hour. While its antihistamine effect begins within ½ to 3 hrs, reaches the maximum at 8 to 12 hours and lasts in excess of 24 hours. If food is present at the time of administration of Loratadine (Loramed), it may delay the absorption of the drug from gut to 1 hour. Loratadine undergoes extensive first pass metabolism, to an active metabolite, descarboethoxy Loratadine. Loratadine is about 98% bound to the plasma protein while its active metabolite descarboethoxy Loratadine is less extensively bound. 80% of the total Loratadine administered is excreted in urine and feces in the form of metabolic product after descarboethoxy Loratadine respectively. Loratadine and descarboethoxy Loratadine are also excreted in the breast milk but do not appear to cross the blood brain barrier to a significant extent.

#### **CLINICAL INDICATIONS:**

Loramed (Loratadine) is indicated for the relief of symptoms associated with;

- Hypersensitivity due to seasonal hay fever.



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- Perennial allergic rhinitis i.e. sneezing, itching, nasal discharge, ocular itching and burning, lacrimation and conjunctivitis.
- Chronic idiopathic urticaria.
- Allergic dermatological disorder like swollen and reddened skin rashes etc.

### DOSAGE AND ADMINISTRATION:

Adult (12 years and above):

10mg: once daily.

Children (2-12 years) more than 30 kg body weight:

5mg: once daily.

Or as prescribed by the physician.

### UNDERIABLE (SIDE) EFFECTS:

Undesirable (side) effects are very rare. In most rare cases headache, sedation, nervousness, fatigue and nausea may occur.

### OVER DOSE:

In the case of over dosage, detoxification by administration of activated charcoal or gastric lavage should be performed.

### CONTRA INDECATIONS:

Loramed (Loratadine) is contra indicated in patients with known hypersensitivity to the drug of idiosyncrasy to any of its components.

### DRUG INTERACTIONS:



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The effect of Loratadine is potentiated, if use concomitantly with erythromycin, cimetidine and ketoconazole by inhibiting hepatic microsomal enzyme system. When administered concomitantly with alcohol, Loratadine has no potentiating effects.

### PRECAUTIONS FOR USE:

Patients suffering from severe liver or renal impairment should be treated cautiously because they may have reduced clearance of Loratadine. The treatment should be started with the initial lower dose of 5mg (1 teaspoonful) daily or 10 mg (2 teaspoonfuls) every other day. Safety has not been established in pregnancy and children less than 2 years of age. It should be discontinued approximately 48 hours prior to skin testing procedure.

### PRECAUTIONS FOR STORAGE/ HANDLING:

- Store in cool and dry place.
- Protect from light.
- Keep out of the reach of children.

### PRESENTATION:

Pack of 60 ml amber colored bottle.

Pack of 10 Tablets in Alu- Alu blister

### FOR THE BENEFIT OF PATIENTS,

#### “IT IS A DRUG”:

- Drug is a product which exerts direct effects on your health, so be very careful. its use against instructions are not favorable for use.
- Strictly follow the physician's prescription, the method of use and his/her other instructions.
- The physician is expert in medicines. He/ She knows its benefits and risks, So do not by yourself change the period of treatment prescribed for you, and do not use the same prescription without consulting your physician.



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