

Patient Information Leaflet

LORATOL®

10 mg tablets

Loratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you notice side effects not mentioned in this leaflet, it is advised to notify the doctor or healthcare professional. Do not pass this medicine on to others.

1. What is LORATOL® and what it is used for

LORATOL® contains loratadine, which belongs to a group of drug called antihistamines. Antihistamines help to relieve the symptoms of some allergies: symptoms of hay fever and other allergies such as sneezing, runny nose and burning, itchy eyes, or symptoms of skin allergies such as rash, itching or urticaria (hives) (ATC code: R06AX13).

2. What you need to know before you take LORATOL® Tablets

- **Do not take LORATOL®** if you are allergic (hypersensitive) to loratadine or to any of the other ingredients.
- Take special care with LORATOL® if you have liver problems: please consult your doctor or pharmacist, maybe you have to take a lower dose.
- **Pregnancy and breast-feeding:** do not take loratadine if you are pregnant or breastfeeding.
- **Taking other medicines:** LORATOL® is not expected to interact with other medicines.
- **Alcohol:** when administered concurrently with alcohol, loratadine has no potentiating effects.
- Antihistamines should be discontinued about four days prior to **skin testing procedures**, since these drugs may prevent or diminish otherwise positive reactions.
- **Driving or using machinery:** In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

3. How to take LORATOL®

Loratol® tablets are administered orally.

Do not exceed the recommended dose.

Adults and children of more than 12 years	Children between 2-12 year	Children below 2 years
1 tablet (10 mg) Loratol® once daily	LORATOL® Suspension should be used instead of the tablet form	Safety and effectiveness is not established

- In patients with liver failure the starting dose should be 10 mg every other day. If the treatment is well tolerated and more efficacy is needed, every day dosing can be considered.
- If symptoms worsen or do not improve talk to your doctor or pharmacist.

4. Possible side effects

Fatigue, nausea and headache are rare.

5. How to store LORATOL® Tablets: Store in the original packaging at a temperature below 30°C. Protect from light. Keep out of the reach and sight of children. Do not use this medicine if the expiry date printed on the pack (Exp.) has passed. Any unused product or waste material should be disposed of in accordance with local requirements.

6. Other information

What LORATOL® Tablets contains: 10 mg Loratadine, lactose monohydrate, maize starch, magnesium stearate.

LORATOL® Tablets is presented in a blister of 10 tablets, each tablet containing 10 mg of loratidine.

LORATOL® Tablets is a prescription only medicine.

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