Patient Information Leaflet

LORATOL®

Suspension 5 mg / 5 ml
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 hayfever and other allergies such as sneezing, runny nose and burning, itchy eyes, symptoms of skin allergies such as rash, itching or urticaria (hives) (ATC code: R06AX13).

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

- **Do not take** LORATOL® if you are allergic (hypersensitive) to loratadine or to any of the other ingredients.
- This medicine can be taken by adults and children aged 2 years and over.
- 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 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.
- This product contains **sucrose**: this should be taken into account if you have diabetes or sugar intolerance.

3. How to take LORATOL®

Loratol® Suspension is administered orally. Shake well before use.
Do not exceed the recommended dose.

Adults and children of more than 12 years	**Children (2-12 years)** **Body weight more than 30kg**	**Children (2-12 years)** **Body weight less than 30kg**
10 mg (10 ml) Loratol® Suspension once daily	10 mg (10 ml) Loratol® Suspension once daily	5 mg (5 ml) Loratol® Suspension once daily

- The safety and effectiveness in children below the age of 2 is not established.
- 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® Suspension: Shelf life: 2 years. Store the syrup in the original packaging at a temperature below 30ºC. Protect from light. Keep out of the reach and sight of children. Do not use this medicine if the expiry date printed on the bottle (Exp.) has passed. Any unused product or waste material should be disposed of in accordance with local requirements.

6. Other information

What LORATOL® Suspension contains: Each 5 ml suspension contains 5 mg loratadine, sodium benzoate, polysorbate 80, propylene glycol, sodium citrate, citric acid, microcrystalline cellulose, carboxymethylcellulose sodium, glycerine, sucrose, Xanthan gum, cherry essence and purified water.

LORATOL® Suspension is presented in a bottle of 100 ml, with a 5 ml spoon**.**

LORATOL® Suspension is a prescription only medicine.

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