Loratol®

loratadine

SYMPTOMATIC TREATMENT OF ALLERGY SYMPTOMS

POSOLOGY	
Children age 2-12: < 30 kg	5 ml / day
Children age 2-12: > 30 kg	10 ml / day
Adolescents > 12	1 tablet / day
Adults	1 tablet / day

STOP allergies

No sedative effects

Dafra Pharma International
Slachthuisstraat 30/7
2300 Turnhout - Belgium.

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Loratol®

loratadine

EUROPEAN GMP

SYMPTOMATIC TREATMENT OF ALLERGY SYMPTOMS

STOP allergies

- RHINITIS
- URTICARIA
- CONJUNCTIVITIS
- SKIN ALLERGY
- WATERY EYES

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COMPOSITION

Loratol® tablet: Loratadine 10 mg.
Box of 10 tablets
Excipients: corn starch, lactose monohydrate, magnesium stearate
Loratol® oral suspension: Loratadine 5 mg/5 ml. 100-ml bottle.
Excipients: Sodium benzoate, polysorbate 80, propylene glycol, sodium citrate, citric acid, microcristalline cellulose, carboxymethylcellulose sodium, glycerine, sucrose, cherry essence and purified water.

INDICATIONS/POSSIBILITIES FOR USE

Children age 2-12 (oral suspension):
Relief of seasonal rhinitis symptoms, such as rhinorrhea, sneezing, nasal and eye burning and itching. Relief of urticaria symptoms.
Adolescents age 12 and older and adults (tablets, oral suspension):
Prophylactic and symptomatic treatment of hay fever, chronic allergic rhinitis, allergic conjunctivitis and chronic urticaria.

DOSAGE/MODE OF USE

Loratol® oral suspension, children age 2-12:
In the case of body weight less than or equal to 30 kg, 1 measuring spoon of Loratol® oral suspension once daily (1 measuring spoon equals 5 ml of oral suspension, or 5 mg of loratadine).
In the case of body weight above 30 kg, 2 measuring spoons of Loratol® oral suspension once daily (2 measuring spoons equal 10 ml of oral suspension or 10 mg of loratadine). The ready to use oral suspension is taken without being diluted with the measuring spoon attached to the package.
Loratol® tablets/oral suspension, adolescents age 12 or older and adults:
One Loratol® tablet or two measuring spoons of Loratol® oral suspension (equivalent to a total of 10 mg of loratadine) once daily. Take the tablets without crushing them with a little liquid.
For fast effect, Loratol® should be taken on an empty stomach. If Loratol® is taken with a meal, its resorption in the blood can be somewhat slowed; however, this will not influence its effectiveness.

SPECIAL DOSAGE INSTRUCTIONS

A smaller dose is recommended in patients with liver disease, i.e., 10 mg of loratadine (1 tablet of Loratol® or 2 measuring spoons of Loratol® oral suspension every two days.

CONTRAINDICATIONS

Loratol® is contraindicated in patients with hypersensitivity to the active ingredient or one of the ingredients of this medication.

WARNINGS AND PRECAUTIONS

Clinical experience is limited with Loratol® oral suspension in children age 2-3, so any such treatment must be undertaken with due caution.
Use Loratol® with caution in the event of simultaneous administration of other drugs metabolised by the liver, especially if hepatic cytochrome P450 3A4 (CYP3A4) and 2D6 (CYP2D6) enzymes participate in their metabolism.

INTERACTIONS

Generally, Loratol® should be used with caution at the same time as other medications metabolised by the liver. Loratol® is metabolised almost completely from the first pass, in which cytochrome P450 3A4 and 2D6 isoenzymes are involved. Pharmacokinetic interactions with drugs also metabolised by these enzymes are therefore probable but without notable changes in clinical laboratory parameters, vital signs or ECG.

PREGNANCY/BREASTFEEDING

In women, usage safety for the substance during pregnancy had not been established. Like other medications, the administration of loratadine is not recommended during pregnancy. Administration of Loratol® is not indicated during breastfeeding because loratadine passes into breast milk.

UNDESIRABLE EFFECTS

Somnolence, headache, increased appetite, insomnia.

Very rarely: vertigo, palpitations, dry mouth, nausea, stomach pain, fatigue, skin rash, allergic reaction.

OVERDOSE

Somnolence, tachycardia and headaches have been reported with an overdose of loratadine (40-180 mg, or 4-18 tablets.

Treatment: to evacuate any medication remaining in the stomach, the usual gastric emptying procedures should be considered.

PHARMACOLOGICAL PROPERTIES

ATC Code: R06AX13

Mechanism of action

Loratadine is a long-acting allergy treatment active orally and non-sedating. It is a specific antagonist of the H1 receptors without central anticholinergic side effect because it does not pass the blood-brain barrier very well. The antihistamine effect starts at the end of 1 to 2 hours and lasts several hours. A single daily dose suffices to control allergy symptoms.

PHARMACOKINETICS

Absorption: Loratadine is resorbed quickly and completely after oral administration. It is subject to a substantial first pass effect and is almost completely metabolised. Its main metabolite is descarboethoxyloratadine (DCL, desloratadine), which also has an anti-H1 effect.

Distribution: Loratadine is 97-99% bound to the plasma proteins and its active metabolite is DCL 73 to 76% bound. Loratadine and its active metabolite are excreted in breast milk. Their concentrations are identical in breast milk and plasma.

Metabolism: Loratadine is almost completely metabolised; cytochrome P450 isoenzymes 3A4 and 2D6 were identified as involved in its metabolism (see also "Interactions").

Elimination: In normal subjects, the mean plasma half-life of loratadine was 8.4 hours on average (3-20 h) and 28 hours (8.8 – 92 h) for its primary metabolite DCL (desloratadine). Around 40% of the dose is eliminated within 10 days in the urine and 42% in the faeces, mainly in the form of its conjugate metabolite. Around 27% of the dose is eliminated in the urine during the first 24 hours.

SPECIAL NOTES

Influence on diagnostic methods: If an allergy test is done, it is necessary to stop Loratol® 4 days before the test is performed, because antihistamine administration can prevent or decrease positive reactions.

Note for diabetics: One measuring spoon of Loratol® (5 ml) contains 3 g of sucrose, which equals 0.25 U.P.

STORAGE

Store below 30°C, in the original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

Do not use the contents of a bottle of Loratol® oral suspension more than six months after opening. Keep the medication out of the reach of children.