PACKAGE LEAFLET:
Information for the user

LORADERM

Syrup - 5 mg / 5 ml
(Loratadine)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LORADERM IS AND WHAT IT IS USED FOR
Loraderm is the name of the product which is presented to the patient in the form of syrup. This syrup has loratadine as active substance. Loratadine is a long-acting non-sedating antihistaminic with weak antimuscarinic activity. Loratadine antagonises the action of histamine due to the competitive ability for H1 receptors of histamine.
Loratadine is used for the symptomatic treatment of allergic states such as:
- rhinitis and chronic urticaria;
- increase in nasal secretions;
- sneezing;
- itchy nose and eyes;
- itchy skin etc.

2. BEFORE YOU TAKE LORADERM
Do not take Loraderm if you are sensitive (allergic) to loratadine (active substance) or to any of the other ingredients of the syrup Loraderm.

Take special care with Loraderm
Ask your doctor before you take Loraderm syrup.
- If you have impaired liver function; in this case the initial dose should be lower.
- If you have impaired renal function; in this case the initial dose should be lower.
- If you suffer from hypertension; loratadine may cause increase of hypertension.
- If you suffer from urinary retension.

The administration of Loraderm syrup should be stopped at least 48 hours before having a skin test; loratadine may prevent, reduce or otherwise produce positive results to the skin indicators.

Taking other medicines
Concomitant treatment with other drugs may affect or be affected by Loraderm syrup.
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Loraderm syrup, if you are given another drug during treatment.

It is particularly important to inform your doctor about the treatment with:
- erythromycin, clarithromycin (antibacterials); they inhibit the metabolism of loratadine;
- ketoconazole (antimycotic); it inhibits the metabolism of loratadine;
- cimetidine (drug for the treatment of stomach ulcer, acidity in stomach and acid reflux).

Pregnancy
Ask your doctor or pharmacist for advice before taking this medicine.
The safety of using loratadine during pregnancy has not been established yet. Therefore, it is not recommended to take this syrup during pregnancy.

Breast-feeding
Loratadine is excreted in breast milk. Therefore, it is not recommended to take this syrup during breastfeeding.

Driving and using machines
The effect of this drug on the ability to drive and use machines is determined after the first doses and it is individual. However, caution is advised in case of driving or performing tasks which require high attention when taking Loraderm syrup.

3. HOW TO TAKE LORADERM
Always take Loraderm syrup as prescribed by your doctor. You should check with your doctor or pharmacist if you are not sure. Please talk to your doctor or pharmacist if the effects of the syrup seem to be too strong or too weak. You can take the syrup with or without food.

Dosage:
- Adults and children over 12 years:
  10 ml syrup (corresponding to 10 mg loratadine) once daily.
- Children aged 2 to 12 years:
  For this patient category the dosage is advised according to the body weight.
  To children weighing more than 30 kg, 10 ml syrup (corresponding to 10 mg loratadine) once daily is advised.
  To children weighing 30 kg or less, 5 ml syrup (corresponding to 5 mg loratadine) once daily is advised.
  The efficacy and safety of loratadine in children below the age of 2 has not been established yet.
- Impaired liver function
  This patient category is recommended to start the treatment with lower doses.
  Adults and children weighing more 30 kg
  An initial dose of 10 mg loratadine which means 10 ml syrup every second day is recommended.
  Children weighing 30 kg or less
  Initially to these children 5 mg loratadine which means 5 ml syrup every second day is recommended.
- Impaired kidney function
  It is not necessary to adjust the dose in elderly patients or patients with impaired kidney function.

If you take more Loraderm syrup than you should
If you take more syrup than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures. Overdosage with loratadine enhances the anticholinergic symptoms due to loratadine use. Drowsiness, tachycardia and headache may be other symptoms of overdose.

If you forget to take the syrup in the right time
If you forget taking one dose (or more doses), take the next dose in its usual time.
Do not take a double dose (or more) to make up for a forgotten dose(s).
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Loraderm syrup also can cause side effects, although not everybody gets them.

Effects on the CNS (Central Nervous System)
Depression of CNS is one of the common side effects of all antihistamines.
Loratadine, as a non-sedating antihistamine, has a low permeability in the CNS and a higher affinity for peripheral H1 histamine receptors compared with those central.
Studies with loratadine have generally shown a lower incidence of sedating capabilities and other effects related to the CNS compared with the observed effects of old antihistaminics, also compared with placebo.

Effects on cardiovascular system
Hypertension, palpitations, tachycardia, syncope.

Dermatologic effects
Dermatitis, dry hair, dry skin, skin itching, photosensitization, increased sweating.

Eye - Ear - Nose - Throat
Blurred vision, ear pain, eye pain, change in taste perception.

Gastrointestinal tract
Dry mouth, abdominal pain, increased appetite and weight gain, nausea, vomiting.

Effects on Urogenital tract
Discoloration of urine, urine retention.

Effects on liver
Abnormal liver function, including jaundice and hepatitis.

Effects on Respiratory System
Difficulty in breathing, dry mucous membranes of the nose, sneezing.

5. HOW TO STORE LORADERM
Keep out of the reach and sight of children.
Do not use Loraderm syrup after the expiry date which is stated on the package.
Do not store above 25°C.
Store the syrup in its original package to protect it from light.

6. FURTHER INFORMATION
What Loraderm syrup contains
The active substance is loratadine.
5 ml syrup contain 5 mg loratadine.
The other ingredients are: propylene glycol, hydroxypropyl methylcellulose, glycerin, sodium saccharin, sodium benzoate, citric acid, disodium EDTA, essence citrus-vanille, purified water.

Contents of the pack
Box with 1 bottle 120 ml.
Box with 1 bottle 150 ml.

Explanatory of the illustration icons on the packaging:


Without medical prescription.


Should not be used during pregnancy.


Content.

Warning.


Syrup.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel./Fax. 00 355 4 23 62 800
Tirana - ALBANIA

This leaflet was last revised in January 2015.

SPECIFICATION

CROPING AREA 15 X 25 cm

PAY ATENTION, all the layers are visible. If you have to print this document please check or uncheck the specific layers.