

Histaclar 10 mg

Film-coated Tablets

loratadine



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may want to read it again.
- If you have any further questions, please 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Histaclar is and what it is used for
2. What you need to know before you take Histaclar
3. How to take Histaclar
4. Possible side effects
5. How to store Histaclar
6. Contents of the pack and other information

1. What Histaclar is and what it is used for

Histaclar belongs to a group of medicines called antihistamines which are used to treat the symptoms of allergies such as with hayfever or year-round allergies, for example from house dust mites.

Histaclar acts to reduce the allergic reactions and their unpleasant symptoms such as sneezing, runny or itchy nose and burning or itchy eyes in adults and children over the age of 2 years and with a body weight more than 30 kg.

Histaclar can also be used to help relieve symptoms of urticaria, an allergic skin reaction like itching, rashes, hives or nettle rash.

2. What you need to know before you take Histaclar

Do not take Histaclar:

- if you are allergic to loratadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Histaclar:

- if you have severe liver problems

During treatment with Histaclar:
If you are due to have some skin tests. You should stop taking Histaclar 48 hours before the test to avoid affecting the test results.

Children and adolescents

Do not give Histaclar to children under 2 years old.
Do not give Histaclar to children between 2 and 12 years old with a body weight less than 30 kg.

Other medicines and Histaclar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is not recommended to take Histaclar during pregnancy.
Histaclar should not be used during breast-feeding as it can pass into breast milk.

Driving and using machines

Very rarely some people experience tiredness while taking Histaclar; if this happens to you it may affect your ability to drive and operate machinery.

Histaclar contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Histaclar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablet with a glass of water. The tablet can be divided into equal doses. You can take Histaclar with or without food.


For adults, the elderly and children over 12 years old: The recommended dose is one tablet per day.

Use in children and adolescents

For children under 12 years with a bodyweight more than 30 kg:
The recommended dose is one tablet per day.

For children under 2 years or with a bodyweight less than 30 kg:
Do not give Histaclar.

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Description		Loratadine 10 mg 30		Date: 10 JUN 2015		Time: 10:13	
Component Type	Leaflet	Pharma Code	TBC	No. of colours	1	Page Count	1/2
Affiliate Item Code	608323	SAP No.	n/a	Colours	<div>Black</div>		
Superceded Affiliate Item Code	516834	Vendor Job No.	256076				
TrackWise PR No.	608323	Trackwise Proof No.	1	Non-Print Colours			
MA No.	PA577/46/1	Glams Proof No.	n/a	Equate CMYK with			
Packing Site/Printer	Laboratorios Lesvi SL	Client Market	Ireland	Main Font	Antique Olive	Body Text Size	9 pt
Supplier Code	n/a	Keyline/Drawing No.	n/a	Dimensions	185 x 270 mm	Min Text Size used	9 pt
		Barcode Info	n/a				
Sign-offs							

For patients with severe liver problems: Your dose may need to be reduced, discuss this with your doctor before taking these tablets.

If you take more Histaclar than you should

Contact your doctor or the nearest casualty department immediately. Take the container and any remaining tablets with you. You might feel sleepy or get a headache or have a fast heart beat.

If you forget to take Histaclar

Take it as soon as possible. However, if you do not remember until the following day, do not take a double dose, to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away.

Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing or swallowing.
Fits

Other possible side effects

Common: may effect up to 1 in 10 people

- Sleepiness

Uncommon: may effect up to 1 in 1,000 people

- Headache
- Increased appetite
- Difficulty sleeping (insomnia)

Very rare: may affect up to 1 in 10,000 people

- Dizziness
- Feeling sick (nausea), dry mouth or inflammation of the stomach (symptoms are pain, vomiting, diarrhoea, nausea)
- Fast heart beat or palpitation
- Liver problems
- Rash or hair loss
- Tiredness (fatigue)

Additional side effects in children

In children aged 2 to 12, headache, nervousness and tiredness (fatigue) were reported as common side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Histaclar

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Histaclar contains

- The active substance is loratadine. Each tablet contains 10 mg loratadine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, pregelatinised starch, hydrated colloidal silica, magnesium stearate, hypromellose, macrogol, carnauba wax and talc.

What Histaclar looks like and contents of the pack

Histaclar 10 mg Film-coated Tablets are white, round with a score line on one side and marked “LR10” on the other side.
The tablets are available in blister packs of 5, 7, 10, 14, 15, 20, 21, 30, 50 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

Laboratorios Lesvi, SL, Avda Barcelona 69, 08970 Sant Joan Despi, Barcelona, Spain.
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Loratadin Arcana 10 mg - Filmtabletten
Belgium	Loratadine Mylan 10 mg filmomhulde tabletten
France	LORATADINE MYLAN 10 mg, comprimé pelliculé
Greece	LORATADINE/GENERICIS F.C TAB 10 mg/TAB
Ireland	Histaclar 10mg film coated Tablets
Luxembourg	Loratadine Mylan 10 mg
Portugal	Loratadina Mylan
The Netherlands	Loratadine Mylan 10 mg, fimlomhulde tabletten
United Kingdom	Loratadine 10mg Film-Coated Tablets

Date leaflet was last revised: 03/2015



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