

Package leaflet: Information for the patient

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 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 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
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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 hayfever and year-round allergies, for example from house dust mites.

Histaclar helps to reduce your allergy symptoms by stopping the effects of a substance called “histamine”, which is produced in the body when you are allergic to something.

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 6 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, pharmacist or nurse before taking Histaclar:

- if you have liver disease.
- if you are due to have any skin tests for allergies. You should stop taking Histaclar 2 days before having these tests. This is because it may affect the test results.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Histaclar Tablets.

Children and adolescents

Do not give Histaclar Tablets to children younger than 6 years old or to children who weigh 30 kg or less. Other more suitable formulations should be used for children younger than 6 years or with a body weight of 30 kg or less.

Children under 2 years of age:

The safety and efficacy of Histaclar 10 mg Film-coated tablets have not been established. No data are available.

Other medicines and Histaclar

Tell your doctor, pharmacist or nurse 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 medicinal product.

3. How to take Histaclar

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse 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.

Use in children and adolescents

It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9 year old child weighs about 30 kg (4st 7lb). If in doubt weigh your child and then follow the instructions in the table.

Do not give to children under 2 years or who weigh 30 kg (4st 7lb) or less.

There may be other formulations of loratadine which may be preferable for children younger than 6 years or with a body weight of 30 kg or less.

How much to take:

Age and weight	How much to take	How often to take
Adults and children 6 years and older who weigh more than 30 kg (4st 7lb)	1 × tablet	Once daily
Children who weigh 30 kg (4st 7lb) or less	Not recommended	
If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.		

If you take more Histaclar than you should

Contact your doctor or pharmacist immediately. Take the container and any remaining tablets with you. No serious problems are expected however, you may feel sleepy or get a headache or have a fast heart beat.

If you forget to take Histaclar

Take it as soon as possible. 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody 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 affect up to 1 in 10 people

- Sleepiness

Uncommon: may affect 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, hair loss
- Tiredness (fatigue)

Not known: frequency cannot be estimated from the available data

- Weight increased

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 HPRAs Pharmacovigilance, Website: www.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

Viatrix Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, 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.

Mylan Hungary Kft., Mylan utca 1., Komárom 2900, Hungary

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

Austria	Loratadin Viatrix 10 mg - Filmtabletten
France	LORATADINE VIATRIS 10 mg, comprimé pelliculé
Ireland	Histaclar 10mg film coated Tablets
Portugal	Loratadina Mylan
The Netherlands	Loratadine Viatrix 10 mg, fimlomhulde tabletten
United Kingdom	Loratadine 10mg Film-Coated Tablets

This leaflet was last revised: October 2024