

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flonidan

10mg tablets

LORATADINE

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

What is in this leaflet?

1. What Flonidan tablets are and what they are used for
2. What you need to know before you take Flonidan tablets
3. How to take Flonidan tablets
4. Possible side effects
5. How to store Flonidan tablets

1. WHAT FLONIDAN TABLETS ARE AND WHAT THEY ARE USED FOR

Flonidan tablets belong to a group of medicines called antihistamines.

Flonidan tablets are used to relieve:

- allergy symptoms such as runny and blocked nose, sneezing, watery eyes (e.g. in hayfever)
- a skin condition with pale or red irregular raised patches and severe itching (urticaria)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLONIDAN TABLETS

Do not take Flonidan tablets and tell your doctor if:

- you are allergic (hypersensitive) to loratadine or any of the other ingredients
- the patient is a child under two years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flonidan tablets if:

- you have liver problems
- the patient is a child with kidney disease

- you are about to have skin tests. Stop taking this medicine at least 48 hours before skin testing.

Other medicines and Flonidan tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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. Flonidan tablets are not recommended in pregnancy or breast-feeding.

Driving and using machines

Flonidan tablets do not cause drowsiness in most people. However, you should not drive or carry out skilled tasks, such as using machinery, until you are certain that you are unaffected in this way.

Flonidan tablets contain lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3. HOW TO TAKE FLONIDAN TABLETS

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

Swallow the tablets whole with water with or without food.

Doses:

- **Adults** (including older people) and children over 12 years of age: One tablet once daily
- **Children 2 to 12 years of age:**
 - Body weight over 30kg:** One tablet once daily
 - Body weight under 30kg:** Not recommended
- **Children aged less than 2 years:** Not recommended.
- **Patients with serious liver problems:**
 - Adults and children with a body weight over 30kg: One tablet every other day.
 - Children with a body weight of 30kg or less: A more suitable dosage form e.g. oral solution, should be taken.

Length of treatment

Flonidan tablets should improve your symptoms, but as with all medicines people may find it does not work for them. If after three days of taking Flonidan tablets your symptoms have not improved, speak to your doctor or pharmacist.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take the container and any remaining tablets with you to show the doctor. Signs of an overdose include sleepiness, fast heart beat and headache.

If you forget to take Flonidan tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

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 everybody gets them.

Stop taking Flonidan tablets and contact your doctor at once if you notice signs of:

- an allergic reaction: swelling of the face, lips, tongue or throat, narrowing of the airways causing difficulty breathing, shock, collapse, rash, itching.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Nervous system: tiredness, sleepiness, inability to sleep, headache, nervousness, dizziness, fits.
- Heart: fast or irregular heart beat.
- Stomach and intestines: increased appetite, feeling or being sick, diarrhoea, indigestion, dry mouth.
- Liver: abnormal liver function (seen in blood tests).
- Skin: hair loss (alopecia).

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLONIDAN TABLETS

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

Do not store above 25°C.

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

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 to protect the environment.

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