

PACKAGE LEAFLET: INFORMATION FOR THE USER

FLONIDAN DIREKT

10 mg Orodispersible 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 this medicine is for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine

1. WHAT THIS MEDICINE IS FOR

This medicine contains Loratadine which belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergies.

It can be used to relieve the symptoms of hayfever (e.g. sneezing, runny and itchy nose and eye irritation) and other allergies such as pet and dust allergies. It can also be used to treat raised, red itchy skin (symptoms of urticaria, which is often known as hives or nettle rash).

2. BEFORE YOU TAKE THIS MEDICINE

This medicine can be taken by adults and children of 12 years and over. This medicine can also be taken by children of 2 to 11 years of age who weigh more than 30 kg (see “How to take this medicine”). However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take:

- **If you are allergic** to any of the ingredients in this medicine
- **If you have phenylketonuria** (this medicine contains aspartame, a source of phenylalanine, which may be harmful to you)

- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose and sorbitol)
- **If you are pregnant or breastfeeding**

Talk to your pharmacist or doctor:

- If you have severe liver problems (you may need to take the medicine less often, see “How to take this medicine”)

Other important information

If you are having any allergy tests, stop taking this medicine 48 hours before the test.

Driving and using machines:

This medicine may make you feel dizzy and very rarely make you feel drowsy. Do not drive or use machinery until you are sure you are not affected.

If you take other medicines

This medicine is not expected to affect any other medicines that you may be taking.

However, some medicines may affect the way that the active ingredient in this medicine is broken down in the body.

If you are unsure about interactions with any other medicines, talk to your pharmacist.

This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

3. HOW TO TAKE THIS MEDICINE

The tablets, which are “melt in the mouth” flavoured tablets, are designed to be placed on the tongue and allowed to completely disintegrate before swallowing. The tablets will normally disintegrate in the mouth in contact with saliva, therefore water or other liquids are not normally needed.

The tablets break easily. Always handle the tablets carefully with dry hands only.

Check the foil is not broken before use. If it is, do not take that tablet.

Tear one blister from the strip along the perforations in the foil. **Don’t push the tablet through the backing foil.** Instead, peel open the backing foil in the direction of the arrow. With dry hands take out the tablet and place immediately on the tongue and allow to completely disintegrate before swallowing.

Giving this medicine to children:

It is important to know how much your child weighs to make sure you give them the correct amount of medicine. As a guide a child of 9 years of age will weigh about 30 kg (four and a half stone). If in doubt weigh your child, then follow the instructions in the table.

Do not give to children who weigh less than 30 kg.

Do not give to children under 2 years.

Adults and children of 12 years and over: Take one tablet once a day.

Children of 2 to 11 years who weigh more than 30 kg: Take one tablet once a day.

Children of 2 to 11 years who weigh less than 30 kg: Do not give this medicine. For children over 2 years of age and who weigh less than 30 kg a syrup form of this medicine may be more suitable.

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.

Do not take more than the amount recommended above.

If symptoms worsen, do not improve or do not go away talk to your pharmacist or doctor.

If you take too many tablets: Talk to your doctor or pharmacist. Taking more tablets than recommended may cause drowsiness, rapid heart beat and headache.

4. POSSIBLE SIDE EFFECTS

Most people will not have problems, but some may get some.

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

These other effects are less serious. If they bother you talk to a pharmacist:

- Other allergic reactions such as skin rash
- Feeling drowsy, dizzy or exhausted, headaches, difficulty sleeping
- Feeling sick, dry mouth, stomach pain, increased appetite
- Fast or irregular heart rate, palpitations
- Hair loss
- Changes in the way your liver works – this may show up in a blood test
- For children of 2 to 11 years of age headaches, feeling exhausted or nervous were more common

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

5. HOW TO STORE THIS MEDICINE

The tablets should be stored in the original packaging, in order to protect from moisture.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the foil or the end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

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