

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flonidan

5 mg/5 ml Oral Suspension

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). 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 aged 2 years and over. 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 loratadine or any of the ingredients in this medicine
- If you have an intolerance to some sugars, unless your doctor tells you to (this medicine contains sucrose)
- If you are pregnant or breastfeeding

Talk to your pharmacist or doctor:

- If you have severe liver problems (you may need a smaller amount of this medicine)

Other important information

If you are having skin patch testing to identify allergies, stop taking this medicine 48 hours before the tests.

Driving and using machines:

This medicine does not normally cause drowsiness in the majority of people taking it. Therefore it will not normally affect your ability to drive or operate machines. However, very occasionally some people do report drowsiness after taking loratadine. If affected do not drive or use machines.

Information about some of the ingredients: This medicine contains 3 g of sucrose per 5 ml spoonful. This should be taken into account if you suffer from sugar diabetes.

If you take other medicines

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

If you are unsure about interactions with any 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

Check the cap seal is not broken before first use. If it is, do not take the medicine.

Shake the bottle well before use. Use the spoon provided.

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. If in doubt weigh your child, then follow the instructions in the table on the back of this leaflet.

Do not give to children under 2 years.

Adults and children of 12 years and over: Take two 5 ml spoonfuls once a day.

Children of 2 to 12 years who weigh more than 30 kg: Take two 5 ml spoonfuls once a day.

Children of 2 to 12 years who weigh less than 30 kg: Take one 5 ml spoonful once a day

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.

This medicine should be swallowed.

Do not take more than the amount recommended above.

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

If you take too much:

Talk to a doctor straight away. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4.POSSIBLE SIDE EFFECTS

Most people will not have problems, but some may get some. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

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

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

If you get any of the following side effects see your pharmacist or doctor:

- Headache, nervousness, tiredness in children

- Drowsiness, headache, increased appetite, difficulty in sleeping in adults
- Fast or irregular heart rate, dizziness, tiredness
- Feeling sick, dry mouth, stomach pain, liver problems, rash, hair loss

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

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 THIS MEDICINE

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 end flap of the carton, or 6 months after first opening. After this date return any unused product to your nearest pharmacy for safe disposal.

Leaflet prepared December 2013