

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALERIX 120MG

Film-coated tablets

FEXOFENADINE HYDROCHLORIDE

• *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 Alerix is and what it is used for
2. What you need to know before you take Alerix
3. How to take Alerix
4. Possible side effects
5. How to store Alerix

1. WHAT ALERIX IS AND WHAT IT IS USED FOR

Alerix contains fexofenadine hydrochloride, which is an antihistamine. Alerix is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALERIX

Do not take Alerix

- if you are allergic to fexofenadine or any of the other ingredients of this medicine

Warnings and precautions

Talk to your doctor or pharmacist before taking Alerix if:

- you have problems with your liver or kidneys
- you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Alerix.

Other medicines and Alerix

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

Indigestion remedies containing aluminium and magnesium may affect the action of Alerix, by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Alerix and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Do not take Alerix if you are pregnant, unless necessary.

Alerix is not recommended during breast-feeding.

Driving and using machines

Alerix is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

3. HOW TO TAKE ALERIX

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

For adults and children aged 12 years and over The recommended dose is one tablet (120 mg) daily. Take your tablet with water before a meal.

If you take more Alerix than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Alerix

doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately and stop taking Alerix if you experience:

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Common side effects (may affect up to 1 in 10 people):

- headache
- drowsiness
- feeling sick (nausea)
- dizziness.

Uncommon side effects (may affect up to 1 in 100 people):

- tiredness
- sleepiness.

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:

- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing.

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 ALERIX

Keep out of the sight and reach of children.

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

This medicinal product does not require any special storage condition. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If the tablets become discoloured or show any other sign of deterioration, seek the advice of your pharmacist.

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor.

Leaflet revision and issue date: 30.04.14