Package leaflet: Information for the user

Fexofenadine hydrochloride 120 mg film-coated tablets

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 of the 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 FEXOFENADINE IS AND WHAT IT IS USED FOR

The name of your medicine is Fexofenadine hydrochloride 120 mg film-coated tablets (called fexofenadine in the leaflet).
It 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 FEXOFENADINE

Do not take Fexofenadine if you:
- are allergic to fexofenadine or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to you doctor or pharmacist before taking fexofenadine if you:
- have problems with your liver or kidneys
- have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- are elderly

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

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

This includes medicines you buy without with prescription, including herbal medicines. This is because fexofenadine can affect the way some other medicines work. Also some medicines can affect the way fexofenadine works.

If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

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

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

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.

Do not take fexofenadine if you are pregnant, unless necessary. Fexofenadine is not recommended during breast-feeding.

Driving and using machines
Fexofenadine 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.

Important information about the ingredients of Fexofenadine
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fexofenadine

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.
This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

If you take more fexofenadine 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 fexofenadine
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.

If you stop taking fexofenadine
Tell your doctor if you want to stop taking fexofenadine before you have finished your course of treatment. If you stop fexofenadine earlier than planned, your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS.

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

Tell your doctor immediately and stop taking fexofenadine if you experience
- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo).

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
- blurred vision
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE FEXOFENADINE

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 and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 fexofenadine 120 mg contains
- The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 120 mg of fexofenadine hydrochloride
- The other ingredients are:
  - Tablet core - microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate.
  - Film coating - hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol, red iron oxide (E172) and yellow iron oxide (E172).

What fexofenadine 120 mg looks like and contents of the pack
Fexofenadine 120 mg film-coated tablets of 6.1 x 15.8 mm are peach coloured, capsule shaped tablets marked with “012” on one side and a scripted “e” on the other.
Fexofenadine is presented in blister packs.
Each tablet is blistered.
Fexofenadine is available in packs of 2 (sample only), 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited,
12 New Fetter Lane,
London EC4A 1JP,
United Kingdom.

Manufacturer

Zentiva Pharma UK Limited,
First floor, Andrews House,
College Road,
Guildford, GU1 4QB,
United Kingdom

This leaflet was last revised in March 2023.

ZENTIVA

[935377]
ZEN-A-0187322-1i-GB-EX
LEAFLET FEXOFENADINE
120MG GB

1873 Pharmacode
1873 Pharmacode
1873 Pharmacode