

Package leaflet: Information for the user

Fexofenadine Hydrochloride 120 mg Film-coated Tablets
(fexofenadine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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1. What Fexofenadine Hydrochloride Tablets is and what it is used for

Fexofenadine Hydrochloride 120 mg Film-coated Tablets (called Fexofenadine Hydrochloride Tablets throughout this leaflet) contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Fexofenadine Hydrochloride Tablets 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 Hydrochloride Tablets

Do not take Fexofenadine Hydrochloride Tablets:

- if you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fexofenadine Hydrochloride Tablets 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 heartbeat
- you are elderly.

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

Other medicines and Fexofenadine Hydrochloride Tablets

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

- 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 Hydrochloride Tablets, by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Fexofenadine Hydrochloride Tablets 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 Hydrochloride Tablets if you are pregnant. This medicine should only be administered if necessary and after medical advice.

Fexofenadine Hydrochloride Tablets is not recommended during breast-feeding.

Driving and using machines

Fexofenadine Hydrochloride Tablets 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.

Fexofenadine Hydrochloride 120 mg Film-coated Tablets contains lactose

Fexofenadine Hydrochloride 120 mg Film-coated Tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fexofenadine Hydrochloride Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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.

Duration of treatment

The duration of treatment may vary depending on the symptoms.

If you take more Fexofenadine Hydrochloride Tablets 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 Hydrochloride Tablets

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

Take the next dose at the usual time.

If you have any further questions on the use of this medicine or if symptoms worsen or do not improve, talk to your pharmacist or doctor.

4. Possible side effects

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

Tell your doctor immediately and stop treatment with Fexofenadine Hydrochloride Tablets 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
- bad dreams
- nervousness
- fast or irregular heartbeat
- diarrhoea
- skin rash and itching
- hives
- blurred vision
- 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. You can also report side effects directly via: HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fexofenadine Hydrochloride Tablets

- 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 after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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.

6. Contents of the pack and other information

What Fexofenadine Hydrochloride Tablets contains

The active substance is fexofenadine hydrochloride. Each tablet contains 120 mg of fexofenadine hydrochloride. The other ingredients are:

- *Tablet core:* Lactose monohydrate, Low-substituted hydroxypropylcellulose, Pregelatinised starch, Colloidal anhydrous silica, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate.
- *Film-coating:* Hypromellose, Povidone, Titanium dioxide, Iron oxide Red, Iron oxide Yellow and Macrogol 400.

What Fexofenadine Hydrochloride Tablets looks like and contents of the pack

Fexofenadine Hydrochloride 120 mg Film-coated Tablets are peach-coloured capsule-shaped film-coated tablets, debossed as '120' on one side and 'FX' on other side.

Fexofenadine Hydrochloride 120 mg Film-coated Tablets are available in Alu-PVC/PVdC, Alu/PVC/PE/ACLAR blisters of 10 and 30 tablets.

Marketing Authorisation Holder

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