

Package leaflet: Information for the user

Fexofenadine Hydrochloride 120mg film coated tablets

Fexofenadine Hydrochloride 180mg film coated tablets

(Fexofenadine hydrochloride)

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. See section 4.

What is in this leaflet

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2. What you need to know before you take Fexofenadine Tablets
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1. What Fexofenadine Tablets are and what they are used for

The active ingredient in your tablets is Fexofenadine hydrochloride, which belongs to a group of medicines called antihistamines. It can be used in adults and adolescents of 12 years and older to relieve the symptoms of:

- 120 mg : hay fever (seasonal allergic rhinitis), such as sneezing, itchy, runny or blocked nose and red, itchy and watery eyes
- 180 mg : long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes
- Fexofenadine Tablets are not suitable for children under 12 years of age.

2. What you need to know before you take Fexofenadine Tablets

Do not take Fexofenadine 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 Tablets if you:

- have problems with your liver or kidneys
- are elderly
- have heart problems, as fexofenadine, like other antihistamines may cause your heart to beat faster (tachycardia) or you feel your heart beating (palpitations).

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

Other medicines and Fexofenadine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. This is especially important for the following medicines:

- Erythromycin (an antibiotic)
- Ketoconazole (a treatment for fungal infections)

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine 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 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 Tablets if you are pregnant, unless necessary. Fexofenadine Tablets are not recommended during breast-feeding.

Driving and using machines

Fexofenadine 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 Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fexofenadine Tablets

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

Dosage:**Adults and adolescents aged 12 years and over**

The recommended dose is one tablet (120 mg or 180 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 Tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest hospital emergency department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

The most common signs of overdose are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Fexofenadine Tablets

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 Tablets

Tell your doctor if you want to stop taking Fexofenadine Tablets before you have finished your course of treatment. If you stop taking Fexofenadine Tablets 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, this medicine can cause side effects, although not everybody gets them.

If you get any of the following symptoms after taking these tablets you should contact your doctor or pharmacist immediately as these may be signs of a serious allergic reaction:

- Swelling of the face, lips, tongue or throat and difficulty breathing.

The following side effects have also been reported:

- **Common** (may affect up to 1 in 10 people):

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

- **Uncommon** (may affect up to 1 in 100 people):

- tiredness or sleepiness

- **Not known (frequency cannot be estimated from the available data):**

- difficulty sleeping (insomnia)
- sleeping disorders

- bad dreams
- nervousness
- fast or irregular heart beat
- diarrhoea
- skin rash and itching,
- hives,
- serious allergic reaction which can cause swelling of the face, lips, tongue or throat
- 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 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 Tablets

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the blister and carton after EXP.

The expiry date refers to the last day of the month.

Store your tablets in the original package.

This medicinal product does not require any special temperature 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 Tablets contains:

The active substance is Fexofenadine hydrochloride.

- Fexofenadine 120 mg film-coated tablet: Each film-coated tablet contains 120 mg of fexofenadine hydrochloride, which is equivalent to 112 mg of fexofenadine
- Fexofenadine 180 mg film-coated tablet: Each film-coated tablet contains 180 mg of fexofenadine hydrochloride, which is equivalent to 168 mg of fexofenadine

The other ingredients are:-

Tablet core:

Microcrystalline Cellulose, Maize Starch, Magnesium Stearate, Croscarmellose Sodium, Povidone.

Film coating:

Hypromellose (E464) , Macrogol (PEG 400), Macrogol (PEG 4000) , Titanium Dioxide (E171), Iron Oxide Yellow (E172). The film-coating on the 120 mg tablet also contains Iron Oxide Red (E172).

What Fexofenadine Tablets looks like and the contents of the pack:

Fexofenadine 120 mg film-coated tablet are peach coloured, oblong, biconvex, film coated tablets.

Fexofenadine 180 mg film-coated tablet are yellow coloured, oblong, biconvex, film coated tablets, plain on one side and with a central breakline on the reverse side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Fexofenadine Tablets are available in PVC/PVDC/Alu blister packs of 7, 10, 15, 20, 30, 50, 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This information is available in alternative formats upon request.

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