

Package leaflet: Information for the user

Fexofenadine 120 MG FILM-COATED TABLETS Fexofenadine 180 MG FILM-COATED TABLETS Fexofenadine hydrochloride

Read all of this leaflet carefully before you start using 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.

IN THIS LEAFLET:

1. What Fexofenadine is and what it is used for
2. What you need to know before you take Fexofenadine
3. How to take Fexofenadine
4. Possible side effects of Fexofenadine
5. How to store Fexofenadine
6. Contents of the pack and other information

1. What Fexofenadine is and what it is used for

Fexofenadine hydrochloride, the active ingredient in your medicine, belongs to the group of medicines known as antihistamines.

Fexofenadine 120 mg tablets are approved for the relief of symptoms such as sneezing, running nose and nose itch, eye itch, tearing and flushing, which typically occur in connection with hay fever (allergic rhinitis).

Fexofenadine 180 mg tablets are approved for the relief of symptoms such as flushing, oedema and itching, which occur in connection with the allergic skin condition called chronic idiopathic urticaria (CIU).

2. What you need to know before you take Fexofenadine

Do not take Fexofenadine if you:

- are allergic (hypersensitive) to fexofenadine hydrochloride or any of the other ingredients of this medicine (Listed in section 6).

The efficacy and safety of fexofenadine hydrochloride has not been studied in children under 12. This medicine is not recommended for children under 12 years of age.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Fexofenadine

- if you are elderly
- if you have kidney or liver problems
- if you have a history of or ongoing heart disease, because taking this kind of medicine may lead to a fast or irregular heart beat.

Talk to your doctor before you take Fexofenadine if:

You are going to take an allergy test. You must stop taking this medicine three days before the test.

Other medicines and Fexofenadine

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

It is especially important to talk to your doctor before you take Fexofenadine if you are also taking any of the following medicines:

- erythromycin, an antibiotic used to treat certain bacterial infections
- ketoconazole, used to treat fungal infections
- lopinavir/ritonavir, used to treat HIV infection.

These medicines increase the amount of Fexofenadine absorbed, and so may increase any side effects you may suffer.

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine by lowering the amount of drug absorbed. If you are taking any such indigestion remedies, it is recommended that you leave about **2 hours** between the time that you take Fexofenadine and your indigestion remedy.

Fexofenadine with food and drink

Fexofenadine should be taken with water.

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.

Pregnancy: Take Fexofenadine during pregnancy only if your doctor considers it to be strictly necessary.

Breast-feeding: It is not recommended to take Fexofenadine if you are breast-feeding.

Driving and using machines

It is unlikely that Fexofenadine will affect your ability to drive or use machines. However, there may be rare exceptions, so please ensure that you are alert before driving or performing tasks demanding your full attention.

Fexofenadine contains 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

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

Fexofenadine 120 mg Tablets: For relief of symptoms of hay fever (allergic rhinitis): The recommended dose is one tablet once daily for adults and children 12 years and older.

Fexofenadine 180 mg Tablets: For relief of symptoms of chronic idiopathic urticaria (allergic skin condition):

The recommended dose is one tablet once daily for adults and children 12 years and older.

Take the tablets with water.

If you think the effects of Fexofenadine are too strong or too weak, please consult your doctor or pharmacist.

If you take more Fexofenadine than you should

Contact your doctor, emergency room or pharmacist if you have taken more Fexofenadine than stated in this leaflet or more than your doctor has prescribed. Symptoms of overdose include dizziness, feeling drowsy, feeling tired and a dry mouth.

If you forget to take Fexofenadine

If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Fexofenadine can cause side effects although not everybody gets them. The side effects described below have been experienced by people taking fexofenadine and they are listed as either common, uncommon or rare.

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

- Headache,
- Drowsiness,
- Nausea,
- Dry mouth,
- Dizziness.

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

- Feeling tired,
- Difficulty sleeping,
- Nervousness,
- Sleep disturbances,
- Bad dreams
- Fast or irregular heartbeat.

Rare (may affect up to 1 in 1,000 people):

- Allergic skin reactions such as eczema,
- Hives and itching,
- Unexpected swelling (oedema),
- Chest tightness,
- Shortness of breath,
- Flushing.

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

- Diarrhoea

Seek medical advice if symptoms of anaphylactic reactions (for example swelling or difficulty breathing) or serious skin reactions occur.

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

- **Keep out of sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and blister.
- The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fexofenadine contains:

The active substance is fexofenadine hydrochloride.

- Each Fexofenadine 120 mg tablet contains 120 mg of fexofenadine hydrochloride equivalent to 112 mg of fexofenadine.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, maize starch, povidone, magnesium stearate. The tablet coat contains hypromellose (E464), titanium dioxide (E171), macrogol 400, macrogol 4000, iron oxide yellow (E172) and iron oxide red (E172).
- Each Fexofenadine 180 mg tablet contains 180 mg of fexofenadine hydrochloride equivalent to 168 mg of fexofenadine.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, maize starch, povidone, magnesium stearate. The tablet coat contains hypromellose (E464), titanium dioxide (E171), macrogol 400, macrogol 4000 and iron oxide yellow (E172).

What Fexofenadine looks like and contents of the pack:

Fexofenadine 120 mg tablets are peach coloured, oblong, film-coated tablets, plain on both sides.

Fexofenadine 180 mg tablets are yellow coloured, oblong, film-coated tablet, plain on one side with a central break-line on the other.

Fexofenadine come in packs of 2, 7, 10, 15, 20, 30, 50, 100 or 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG.

Company responsible for manufacture: Chanelle Medical, Loughrea, Co. Galway, Ireland

Product licence number(s)

Fexofenadine 120mg Film-coated Tablets: PL 00289/1030

Fexofenadine 180mg Film-coated Tablets: PL 00289/1031

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