

PACKAGE LEAFLET: INFORMATION FOR THE USER



Fexofenadine Hydrochloride 180mg Film-Coated Tablets

Fexofenadine Hydrochloride 180mg Film-Coated Tablets will also be referred to in this leaflet as Fexofenadine 180mg Tablets.
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 have 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 after taking this medicine.

What is in this leaflet:

1. What Fexofenadine 180mg Tablets are and what they are used for
2. What you need to know before you take Fexofenadine 180mg Tablets
3. How to take Fexofenadine 180mg Tablets
4. Possible side effects
5. How to store Fexofenadine 180mg Tablets
6. Contents of the pack and other information

1. WHAT FEXOFENADINE 180MG 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 is used in adults and adolescents of 12 years and older to relieve the symptoms of urticaria (red, raised itchy skin) which is often known as hives or nettle rash.

Fexofenadine 180mg Tablets are not suitable for children under 12 years of age. You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEXOFENADINE 180MG TABLETS

Do not take Fexofenadine 180mg 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 180mg Tablets if you:

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

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist before taking Fexofenadine 180mg Tablets.

Other medicines and Fexofenadine 180mg Tablets

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

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

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 180mg 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 180mg Tablets and your indigestion remedy.

Fexofenadine 180mg Tablets with food and drink

Fexofenadine 180mg Tablets should be taken before meals with water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fexofenadine 180mg Tablets should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines

Fexofenadine 180mg Tablets are 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 180mg Tablets contain Allura Red AC Lake, which may cause allergic reactions.

Fexofenadine 180mg 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 180MG 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 adolescents aged 12 years and over

The recommended dose is one tablet (180mg) 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 the symptoms of allergic skin reactions persist, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Do not exceed the stated dose. Do not give to adolescents below 12 years of age.

If you take more Fexofenadine 180mg Tablets than you should

If you have accidentally taken more than this leaflet recommended, contact the 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 180mg Tablets

Do not take a double dose to make up for a forgotten tablet. Take the next dose at the usual time.

If you stop taking Fexofenadine 180mg Tablets

Tell your doctor if you want to stop taking Fexofenadine 180mg Tablets before you have finished your course of treatment. If you stop taking Fexofenadine 180mg 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 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.

Not known (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 reaction which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness
- difficulty breathing
- blurred vision.

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 website: 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 180MG 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 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 180mg Tablets contain

The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 180mg of fexofenadine hydrochloride, equivalent to 168mg of fexofenadine.

The other ingredients (excipients) are:

Tablet core: powdered cellulose, mannitol (E421), maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
 Tablet coating: opadry pink film-coating mixture containing hypromellose (E464), titanium dioxide (E171), macrogol 400, allura red AC lake (FD&C Red #40) (E129), and iron oxide, black (E172)

What Fexofenadine 180mg Tablets look like and contents of the pack

Fexofenadine 180mg Tablets are pink coloured, oval, tablets marked with "FXF" on one side and "180" on the other side.

Fexofenadine 180mg Tablets are packed in blister strips packaged in cartons.

The cartons contain 7, 10, 14, 15, 20, 21, 28 or 30 Tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, UK.

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