

PATIENT INFORMATION LEAFLET
Fexofast 120mg and 180 mg Film-Coated Tablets
(Fexofenadine Hydrochloride)

The name of this medicine is Fexofast 120 mg & 180 mg Film-Coated Tablets which will be referred to as FexoFast Tablets throughout this leaflet.

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 your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist. See section 4

What is in this leaflet

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1. WHAT FEXOFAST 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 to relieve the symptoms of

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEXOFAST TABLETS

Do not take FexoFast tablets :

- If you have ever had a reaction to fexofenadine or any of the other ingredients of the tablets (see section 6 for a full list of ingredients), or if you suspect that you are allergic to any of these ingredients

Take special care with Fexofast Tablets

Before you take FexoFast Tablets you should tell your doctor :

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

Taking other medicines

Please tell your doctor if you are taking or have recently taken any of the following medicines, as they may decrease or increase the effects of FexoFast Tablets and vice versa.

- Erythromycin (an antibiotic)
- Ketoconazole (a treatment for fungal infections)
- Antacids containing aluminium and magnesium

It is recommended that you leave about 2 hours between the time that you take FexoFast Tablets and your antacids.

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

It may still be alright for you to take FexoFast Tablets and your doctor will be able to decide what is suitable for you.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Fertility, pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you might be pregnant, are planning to become pregnant or are breast-feeding.

Do not take FexoFast Tablets if you are pregnant, unless prescribed. FexoFast Tablets are not recommended during breast-feeding.

Driving and using machines

It is unlikely that FexoFast Tablets will affect your ability to drive or use machines. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

FexoFast Tablets 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 FEXOFAST TABLETS

Always take FexoFast Tablets exactly as your doctor has told you to do so. You should check with your doctor or pharmacist if you are not sure.

Dosage

Adults and children aged 12 years and over

The recommended dose is one tablet (120mg or 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.

Children aged under 12 years

Fexofenadine is not suitable for children under 12 years.

If you take more FexoFast Tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest hospital casualty 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 FexoFast Tablets

Simply leave out that dose and then take your next dose at the right time. **Do not** take a double dose or make up for a missed dose.

If you stop taking FexoFast Tablets

Tell your doctor if you want to stop taking FexoFast Tablets before you have finished your course of treatment. If you stop taking FexoFast Tablets earlier than planned, your symptoms may return. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, FexoFast Tablets 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 undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug (placebo).

Common (occurring in less than 1 in 10 people):

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

Uncommon (occurring in less than 1 in 100 people):

- tiredness and 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 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, and 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 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 FEXOFAST TABLETS

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date (Exp.) stated on both blister and carton. The expiry date refers to the last day of that month.

Store your tablets in the original package.

This medicinal product does not require any special temperature storage condition.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What FexoFast Tablets contain**

The active ingredient is Fexofenadine hydrochloride. Each Film-Coated tablet contains 120 mg or 180mg of Fexofenadine hydrochloride.

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 120mg Tablet also contains Iron Oxide Red (E172).

What FexoFast Tablets looks like and contents of the pack:

FexoFast 120mg Film-coated tablets are peach coloured, oblong, biconvex, film coated tablets.

FexoFast 180mg Film-coated tablets are yellow coloured, oblong, biconvex, film-coated tablets, plain on one side and with a central breakline on the reverse side. This breakline allows the division of the tablet.

Your medicine is available in PVC/PVDC foil blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer:

Cipla Europe NV, De Keyserlei, 58-60, Box-19, Antwerp, 2018, Belgium

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

This information is available in alternative formats upon request.

This leaflet was last approved in February 2023.