

**Package leaflet: Information for the patient**

**Fexofenadine Hydrochloride 180 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.**

- 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.

The name of your medicine is Fexofenadine Hydrochloride 180 mg Film-coated Tablets (referred to as Fexofenadine Hydrochloride Tablets throughout this leaflet).

**What is in this leaflet**

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

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

Fexofenadine Hydrochloride Tablets contains fexofenadine hydrochloride, which is an antihistamine.

Fexofenadine Hydrochloride Tablets is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

**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**

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Fexofenadine Hydrochloride Tablets if you are pregnant, unless necessary.

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 180 mg Film-coated Tablets contains lactose**

Fexofenadine Hydrochloride 180 mg Film-coated Tablets contain 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 your doctor 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 (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 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 as prescribed by your doctor.

### **If you stop taking Fexofenadine Hydrochloride Tablets**

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

If you stop taking Fexofenadine Hydrochloride 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.

**Tell your doctor immediately and stop taking 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.

**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](http://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 180 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 180 mg Film-coated Tablets are peach coloured capsule shaped film-coated tablets, debossed as '180' on one side and 'FX' on other side.

Fexofenadine hydrochloride 180 mg Film-coated Tablets are available in Alu-PVC/PVdC, Alu/PVC/PE/ACLAR blisters of 10 tablets and HDPE bottle packs of 500 and 1000 tablets.

**Marketing Authorisation Holder**

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**Manufacturer**

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