

<b>FEXOFENADINE HYDROCHLORIDE 120 MG FILM COATED TABLETS</b>		
<b>MODULE 1</b>	ADMINISTRATION AND PRESCRIBING INFORMATION	
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**PATIENT INFORMATION LEAFLET  
(PIL)**

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## PACKAGE LEAFLET: INFORMATION FOR THE USER

### FEXO ALLERGY RELIEF 120 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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. 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

#### **What is in this leaflet:**

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

#### **1. What Fexo Allergy Relief is and what it is used for**

Fexo Allergy Relief contains fexofenadine hydrochloride which is a non-drowsy antihistamine.

Fexo Allergy Relief 120 mg tablets are used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, running or blocked nose and itchy, red and watery eye).

#### **2. What you need to know before you take Fexo Allergy Relief**

##### **Do not take Fexo Allergy Relief:**

- 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 Fexo Allergy Relief 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.
- if you are elderly.

If any of these apply to you, or if you are not sure, tell your doctor before taking Fexo Allergy Relief.

##### **Other medicines and Fexo Allergy Relief**

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 or magnesium may affect the action of Fexo Allergy Relief by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Fexo Allergy Relief and your indigestion remedy.

If you are taking fexofenadine together with erythromycin or ketoconazole, or with a single dose of lopinavir and ritonavir combination, the level of fexofenadine in your plasma may increase. It is possible that the side effects may increase.

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### **Taking Fexo Allergy Relief with food and drink**

Fexo Allergy Relief 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.

Do not take Fexo Allergy Relief if you are pregnant. This medicine should only be administered if necessary and after medical advice.

Fexo Allergy Relief is not recommended during breast-feeding.

### **Driving and using machines.**

Fexo Allergy Relief 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.

### **Fexo Allergy Relief contains sodium.**

This medicine contains less than 1 mmol sodium (23 mg) per 120 mg Fexo Allergy Relief film-coated tablets that is to say essentially 'sodium-free'.

## **3. How to take Fexo Allergy Relief**

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:**

Fexo Allergy Relief 120 mg Tablets: The recommended dose is one tablet (120 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.

### **Duration of treatment**

The duration of treatment may vary depending on the symptoms.

### **If you take more Fexo Allergy Relief 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 a dry mouth.

### **If you forget to take Fexo Allergy Relief**

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 Fexo Allergy Relief**

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

If you stop taking Fexo Allergy Relief 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 Fexo Allergy Relief if you experience:**

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo).

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**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
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly Ireland 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 Fexo Allergy Relief**

Keep this medicine out of 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 Fexo Allergy Relief contains**

- The active substance is fexofenadine hydrochloride.

Each Fexo Allergy Relief 120 mg tablet contains 120 mg of fexofenadine hydrochloride.

- The other ingredients are:
  - *Tablet core*: microcrystalline cellulose, croscarmellose sodium, maize starch, povidone, magnesium stearate.
  - *Tablet coat*: hypromellose (E464), titanium dioxide (E171), macrogol 400, macrogol 4000, iron oxide yellow (E172) and iron oxide red (E172).

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**What Fexo Allergy Relief looks like and contents of the pack**

Fexo Allergy Relief 120 mg tablets are peach coloured, oblong, film-coated tablets, plain on both sides. Fexo Allergy Relief comes in packs of 2, 7, 10, 15, 20, 30, 50, 100 or 200 tablets; not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

**Manufacturer**

Chanelle Medical Unlimited Company, Loughrea, Co Galway, Ireland

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