

**PACKAGE LEAFLET: INFORMATION FOR THE USER****FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS  
FEXOFENADINE HYDROCHLORIDE 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 symptoms 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 hydrochloride is and what it is used for
2. What you need to know before you take Fexofenadine hydrochloride
3. How to take Fexofenadine hydrochloride
4. Possible side effects of Fexofenadine hydrochloride
5. How to store Fexofenadine hydrochloride
6. Contents of the pack and other information

**1. WHAT FEXOFENADINE HYDROCHLORIDE IS AND WHAT IT IS USED FOR**

**FEXOFENADINE HYDROCHLORIDE** contains fexofenadine hydrochloride which is an antihistamines.

Fexofenadine hydrochloride 120 mg tablets is 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 ).

Fexofenadine hydrochloride 180 mg 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****Do not take Fexofenadine hydrochloride:**

- 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 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 heart beat.
- if you are elderly.

If any of these apply to you, or if you are not sure, tell your doctor before taking Fexofenadine hydrochloride

**Other medicines and Fexofenadine hydrochloride**

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 Fexofenadine hydrochloride 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 and you 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.

**Taking Fexofenadine hydrochloride with food and drink**

Fexofenadine hydrochloride should be taken with water.

**Pregnancy and breast-feeding**

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

Do not take Fexofenadine hydrochloride if you are pregnant unless necessary.

Fexofenadine hydrochloride is not recommended during breast-feeding.

**Driving and using machines**

Fexofenadine hydrochloride 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.

This medicine contains less than 1 mmol sodium (23 mg) per 120/ 180 mg Fexofenadine hydrochloride film-coated tablets that is to say essentially 'sodium-free'.

**3. HOW TO TAKE FEXOFENADINE HYDROCHLORIDE**

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:**

**Fexofenadine hydrochloride 120 mg Tablets:** The recommended dose is one tablet (120 mg) daily. Take your tablet with water before a meal.

**Fexofenadine hydrochloride 180 mg Tablets:** The recommended dose is one tablet (180 mg) daily. Take your tablet with water before a meal.

**If you take more Fexofenadine hydrochloride 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 Fexofenadine hydrochloride**

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**

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

If you stop taking Telfast 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 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 heart beat
- 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.
- 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 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 FEXOFENADINE HYDROCHLORIDE

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 Fexofenadine hydrochloride contains**

- The active substance is fexofenadine hydrochloride.

Each Fexofenadine hydrochloride 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).

Each Fexofenadine hydrochloride 180 mg tablet contains 180 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 and iron oxide yellow (E172).

#### **What Fexofenadine hydrochloride looks like and contents of the pack**

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

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

Fexofenadine hydrochloride 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**

Chanelle Medical Unlimited Company, Loughrea, Co Galway, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

NAME OF MEMBER STATE	NAME OF MEDICINAL PRODUCT
Denmark	Clarifast 120 mg, filmovertrukne tabletter Clarifast 180 mg, filmovertrukne tabletter
Ireland	Fexofenadine hydrochloride 120 mg film-coated tablets Fexofenadine hydrochloride 180 mg film-coated tablets
The Netherlands	Fexofenadine HCL ratiopharm 120 mg Fexofenadine HCL ratiopharm 180 mg
Poland	Telfexo 120 mg Telfexo 180 mg

This leaflet was last updated in February 2023