PACKAGE LEAFLET: INFORMATION FOR THE USER

FLIXRELIEF 120MG FILM COATED TABLETS
fexofenadine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your pharmacist has 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.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. Always use 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 X days.

In this leaflet:

1. What Flixrelief 120mg Film Coated Tablets is and what it is used for
2. What you need to know before you take Flixrelief 120mg Film Coated Tablets
3. How to take Flixrelief 120mg Film Coated Tablets
4. Possible side effects
5. How to store Flixrelief 120mg Film Coated Tablets
6. Contents of the pack and other information

1. WHAT FLIXRELIEF 120MG FILM COATED TABLETS IS AND WHAT IT IS USED FOR

Flixrelief 120mg Film Coated Tablets contain fexofenadine hydrochloride which is a non-drowsy antihistamine.

Flixrelief 120mg Film Coated Tablets is used in adults and adolescents of 12 years of age and older to relieve the symptoms that occur with allergic rhinitis (for example hayfever) such as sneezing, itchy, running or blocked nose and itchy, red and watery eyes.

Formatted: English (United Kingdom)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLIXRELIEF 120MG FILM COATED TABLETS

Do not take Flixrelief 120mg Film Coated 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 Flixrelief 120mg Film Coated Tablets:
- if you have problems with your liver or kidneys.
- if 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 Flixrelief 120mg Film Coated Tablets.

Other medicines and Flixrelief 120mg Film Coated 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 Flixrelief 120mg Film Coated Tablets by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Flixrelief 120mg Film Coated Tablets and your indigestion remedy

Pregnancy and breast-feeding
If you are pregnant, breast-feeding or 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 Flixrelief 120mg Film Coated Tablets if you are pregnant, unless advised by a doctor.
Flixrelief 120mg Film Coated Tablets is not recommended during breast-feeding

Driving and using machines
Flixrelief 120mg Film Coated 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.

Flixrelief 120mg Film Coated Tablets **contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW TO TAKE FLIXRELIEF 120MG FILM COATED TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 (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.
Flixrelief 120mg Film Coated Tablets is not recommended for children under 12 years of age.

If you take more Flixrelief 120mg Film Coated 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 Flixrelief 120mg Film Coated Tablets
Do not take a double dose to make up for a forgotten tablet. Take the next dose at the usual time.

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.

Stop taking the medicine and seek immediate medical help 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
- diarrhea
- 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 pharmacist. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLIXRELIEF 120MG FILM COATED TABLETS

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 and blister after 'EXP'. The expiry date refers to the last day of that month.

Keep the blister in the outer carton in order to protect from light and moisture.

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 Flixrelief 120mg Film Coated Tablets contains
- The active substance is fexofenadine hydrochloride.

Each film coated tablet contains 120 mg of fexofenadine hydrochloride
- The other ingredients are:
  - *Tablet core:* microcrystalline cellulose, croscarmellose sodium, maize starch, povidone k-30, magnesium stearate.

- *Tablet coat*: hypromellose (E464), titanium dioxide (E171), macrogol 400, macrogol 4000, iron oxide yellow (E172) and iron oxide red (E172).

What Flixrelief 120mg Film Coated Tablets look like and contents of the pack
Flixrelief 120mg Film Coated Tablets are peach-coloured, oblong, biconvex film-coated tablets.

Flixrelief 120mg Film Coated Tablets is available in blisters containing 2, 7, 10, 15, 20, 30 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Haleon Ireland Limited, Clocherane, Dungarvan, Co.Waterford, Ireland
Manufacturer
Chanelle Medical Unlimited Company, Loughrea, Co. Galway Ireland.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark: Otrafexi 120 mg filmovertrukne tabletter
Ireland: Flixrelief 120 mg film-coated tablets
Finland: Otrafexi 120 mg kalvopäällysteiset tabletit
Sweden: Otrafexi 120 mg filmdragerade tabletter
Iceland: Otrafexi 120 mg filmuhúðaðar töflur
Belgium: OtriFex 120 mg filmomhulde tabletten
Luxembourg: OtriFex 120 mg filmomhulde tabletten
The Netherlands: OtriFex 120 mg filmomhulde tabletten

This leaflet was last revised in May 2026