

Package leaflet: Information for the user

Fexofenadine hydrochloride 120 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.

What is in this leaflet:

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

1. What Fexofenadine is and what it is used for

Fexofenadine hydrochloride 120 mg film-coated-tablets (called Fexofenadine throughout this leaflet) contains fexofenadine hydrochloride, which is an antihistamine.

Fexofenadine 120 mg 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, runny or blocked nose and itchy, red and watery eyes.

2. What you need to know before you take Fexofenadine

Do not take Fexofenadine

- 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 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.

Other medicines and Fexofenadine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine, by lowering the amount of medicinal product absorbed.

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

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 Fexofenadine if you are pregnant, unless necessary.

Fexofenadine is not recommended during breast-feeding.

Driving and using machines

Fexofenadine 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.

3. How to take Fexofenadine

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 (120 mg) daily.

Take your tablet with water before a meal.

If you take more Fexofenadine 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

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

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

If you stop taking Fexofenadine 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 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.

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 (*see details below*). *By reporting side effects you can help provide more information on the safety of this medicine.*

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. How to store Fexofenadine

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 and blister after [to be completed nationally]. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 protect the environment.

6. Contents of the pack and other information

What Fexofenadine 120 mg contains

The active substance is fexofenadine hydrochloride. Each tablet contains 120 mg of fexofenadine hydrochloride.

The other ingredients are:

Tablet core: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film coating: hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Fexofenadine 120 mg looks like and contents of the pack

Fexofenadine hydrochloride 120 mg film-coated tablets are peach coloured, modified capsule-shaped tablets marked with “012” on one side and a scripted “e” on the other.

Fexofenadine is presented in PVC/PE/PVDC/Al or PVC/PVDC/Al blister packs packaged into cardboard boxes.

Fexofenadine is available in packs of 2 (sample only), 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

In the UK:

Sanofi-aventis, One Onslow Street, Guilford,

Surrey, GU1 4YS, UK

Tel: 01 483 505515

Fax: 01483 535432

Email: uk-medicalinformation@sanofi-aventis.com

In Ireland:

Sanofi-aventis Ireland Limited., T/A SANOFI

Citywest Business Campus, Dublin 24, Ireland

Tel: 00353 (0) 4035600

Fax: 00353 (0)4035601

Email: IEmedinfo@sanofi-aventis.com

Manufacturer:

Sanofi Winthrop Industrie,

30-36 Avenue Gustave Eiffel,

37100 Tours, France

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

Denmark: Allegra

Finland: Allegra 120 mg kalvopäällysteiset tabletit

Ireland: Fexofenadine Hydrochloride 120 mg film coated tablets

Malta: Allegratab 120 mg film coated tablets

United Kingdom: Fexofenadine Hydrochloride 120 mg film coated tablets

This leaflet was last approved in