

Package leaflet: Information for the user

Telfast® Allergy 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.

Always take this medicine exactly as described in this leaflet or as your doctor or 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.

What is in this leaflet:

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

1. What Telfast Allergy is and what it is used for
Telfast Allergy 120 mg film-coated-tablets (called Telfast Allergy throughout this leaflet) contains fexofenadine hydrochloride, which is a non-drowsy antihistamine. Telfast Allergy is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with allergy rhinitis (for example hay fever) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. What you need to know before you take Telfast Allergy

Do not take Telfast Allergy

- 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 Telfast Allergy 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
- you are elderly.

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

Other medicines and Telfast Allergy

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 Telfast Allergy, by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Telfast Allergy 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 Telfast Allergy if you are pregnant. This medicine should only be administered if necessary and after medical advice.

Telfast Allergy is not recommended during breast-feeding.

Driving and using machines

Telfast Allergy 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.

Telfast Allergy contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Telfast Allergy

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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.

Duration of treatment

The duration of treatment may vary depending on the symptoms.

If you take more Telfast Allergy 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 Telfast Allergy

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 or if symptoms worsen or do not improve, talk to your pharmacist or doctor.

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 Telfast Allergy 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 patient who did not receive the drug (placebo).

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 Telfast Allergy

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 EXP. The expiry date refers to the last day of that month.

This medicinal product should be stored away from 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 protect the environment.

6. Contents of the pack and other information

What Telfast Allergy 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 red iron oxide and yellow iron oxide (E172)

What Telfast Allergy looks like and contents of the pack

Telfast Allergy 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. Cartons contain blister packs. 30 tablets are supplied in each pack. Each blister strip contains 15 tablets.

Manufacturer

Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37 100 Tours, France.

Product procured from within the EU, repackaged and distributed by the PPA Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PPA Number: PPA0465/500/001

Telfast is a registered trademark of AVENTISUB LLC.

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

Denmark: Allegra

Ireland: Telfast Allergy 120 mg film coated tablets

Malta: Allegratab 120 mg film coated tablets