Package leaflet: Information for the user

TELFAST 180 mg film-coated tablets
Fexofenadine hydrochloride

Is this leaflet hard to see or read?
In Ireland phone +353 1 4035600 for help

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 Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Telfast 180 mg 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 Telfast

Do not take Telfast
- 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 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.

Other medicines and Telfast
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, by lowering the amount of medicinal product absorbed.
It is recommended that you leave about 2 hours between the time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Do not take Telfast if you are pregnant, unless necessary.
Telfast is not recommended during breast-feeding.

Driving and using machines
Telfast 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 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

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 (180 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.

If you take more Telfast 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
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 Telfast
Tell your doctor if you want to stop taking Telfast 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 Telfast 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Ireland:
You can also report side effects directly via HPRA Pharmacovigilance
Website: www.hpra.ie
Malta:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Telfast

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 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 protect the environment.

6. Contents of the pack and other information

What Telfast 180 mg contains
● The active substance is fexofenadine hydrochloride. Each tablet contains 180 mg of fexofenadine hydrochloride.
● The other ingredients are:
○ *Tablet core:* microcrystalline cellulose, pregelatinized maize starch, croscarmellose sodium, magnesium stearate.
○ *Film coating:* hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Telfast 180 mg looks like and contents of the pack
Telfast 180 mg film-coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and a scripted "e" on the other.
Telfast is presented in blister packs. Each tablet is blistered.
Telfast is available in packs of 2 (sample only), 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 Ireland:
Opella Healthcare France SAS, T/A Sanofi,
82 Avenue Raspail, 94250 Gentilly, France.
Tel: +353 1 4035600
email: IEmedinfo@sanofi.com

In Malta:
Sanofi S.r.l
Viale Luigi Bodio 37/b
20158 Milan (Italy).

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:
Belgium: Allegra tab 180 mg filmomhulde tabletten
Denmark: Telfast, filmovertrukne tabletter 180 mg
Finland: Telfast 180 mg tabletti, kalvopäällysteinen
Germany: Telfast 180 mg
Ireland: Telfast 180 mg film-coated tablets
Italy: Telfast 180 mg compresse rivestite con film
Luxembourg: Allegra tab 180 mg filmomhulde
tabletten Malta: Telfast 180 mg film-coated tablets
Portugal: Telfast 180, comprimidos revestidos por película
Spain: Fexofenadina Opella 180 mg comprimidos recubiertos
con película
Sweden: Telfast 180 mg filmdragerade tabletter
United Kingdom: Telfast 180 mg film coated tablets

This leaflet was last revised in January 2023.