

PACKAGE LEAFLET: INFORMATION FOR THE USER

Telfast® 180mg Film Coated Tablets (fexofenadine hydrochloride)

Your medicine is available using the above name, but will be referred to as Telfast throughout this leaflet.

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
2. What you need to know before you take Telfast
3. How to take Telfast
4. Possible side effects
5. How to store Telfast
6. Contents of the pack and other information

1. What Telfast is and what it is used for

Telfast contains fexofenadine hydrochloride, which is an antihistamine.

Telfast 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.

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.

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 (180mg) 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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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 (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.

There are no special storage conditions for this medicine.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Telfast contains

Each tablet contains 180mg of fexofenadine hydrochloride (equivalent to 168mg of fexofenadine).

The tablets also contain: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate, hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400, and iron oxide (E172).

What Telfast looks like and contents of the pack

Telfast 180mg are peach, modified capsule-shaped, film-coated tablets debossed with 'e' on one side and '018' on the other.

Your medicine is available in packs containing 30 tablets.

Manufacturer

Manufactured by: Sanofi Winthrop Industrie,
30 - 36 avenue Gustave Eiffel, 37100 Tours, France.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

PPA No: 1151/80/2

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Telfast® is a registered trademark of Aventis Inc.

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

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

Blind or partially sighted?
Is this leaflet hard to see or
read?
Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the
following information:
Product name: Telfast
180mg Film Coated Tablets
Reference No: 1151/80/2