

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

# Telfast 120 mg Film-coated tablets

Fexofenadine hydrochloride

sanofi aventis



**Is this leaflet hard to see or read?**

**In the UK Phone 01483  
505515 for help  
In Ireland Phone 01 403  
5600 for help**

**Read all of this leaflet carefully before you start taking this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**In this leaflet:**

1. What Telfast is and what it is used for
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**1. What Telfast is and what it is used for**



Telfast contains fexofenadine hydrochloride, which is an antihistamine. Telfast 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. Before you take Telfast**



**Do not take Telfast**

- × if you are allergic (hypersensitive) to fexofenadine or any of the other ingredients of Telfast (see section 6 for a full list of ingredients).



**Take special care with Telfast**

- ▲ 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 heart beat
- ▲ if you are elderly

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



**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast, by lowering the amount of drug 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 Telfast exactly as your doctor has told you.

You should 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 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 product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Telfast 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 (occurring in less than 1 in 10 but more than 1 in 100 patients): headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but more than 1 in 1,000 patients): difficulty sleeping (insomnia), tiredness/sleepiness, sleeping disorders, bad dreams, nervousness, fast or irregular heart beat and diarrhoea.

Rare side effects (occurring in less than 1 in 1,000 but more than 1 in 10,000 patients): skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat and difficulty breathing.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5. How to store Telfast

Keep out of the reach and sight of children.

Do not use Telfast after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Further information

##### What Telfast 120 mg contains

The active substance of Telfast 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 Telfast 120 mg looks like and contents of the pack

Telfast 120 mg film-coated tablets are peach coloured, capsule shaped tablets marked with "012" on one side and "e" on the other.

Telfast is presented in blister packs. Each tablet is blistered.

Telfast 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:

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###### Manufacturer:

Sanofi Winthrop Industrie,  
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##### This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Telfast 120 mg-Filmtabletten

Belgium: Telfast 120 mg filmomhulde tabletten

Denmark: Telfast, filmovertrukne tabletter 120 mg

Finland: Telfast 120 mg tabletti, kalvopäällysteinen

Germany: Telfast 120 mg-Filmtabletten

Ireland: Telfast 120 mg film-coated tablets

Italy: Telfast 120 mg compresse rivestite con film

Portugal: Telfast 120, comprimidos revestidos por película

Spain: Telfast 120 mg comprimidos recubiertos con película

Sweden: Telfast 120 mg filmdragerade tabletter

United Kingdom: Telfast 120 mg film-coated tablets

**This leaflet was last approved in 01/2009**