

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**TELFAST 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 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

The name of this medicine is Telfast 120 mg film-coated tablets, referred to as Fexofenadine throughout this leaflet.

Fexofenadine is an antihistamine.

It 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 heart beat
- 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. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

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 via the Yellow card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

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. 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 K30, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400, red iron oxide (E172) and yellow iron oxide (E172).

What fexofenadine 120 mg looks like and contents of the pack

Fexofenadine 120 mg film-coated tablets of 6.1 x 15.8 mm are peach coloured, capsule shaped tablets marked with "012" on one side and a scripted "e" on the other.

Each blister pack contains 30 tablets.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

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This leaflet was last updated in 09/2016



SANOFI 

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Plant PM code : **650817**
Update : V1 - 09/SEP./2016
Local code : N.A.
Old PM code : 619763
Name : **NT.FEXOFENADINE 120MG
RL S1**
Country : **GB**
Plant : Tours TN
Supplier code : N.A.

Technical Data

Format : 210 x 170 mm - *Rouleau* - Simple
Sens de déroulement :
Recto Intérieur_4A (Portrait) - Verso Ext. : 4B
Plant barcode : *650817*
Colors : 1
- **Noir PMS BLACK U**
Fonts : Ocean Sans Pro SAN (Mini : 10,5Pts) - L39HrP24Dh -
Arial (bullet points o : 7pts)
Assembly Card : N.A.
Layout of Cutting : TN_LCG_NTRL_13c
Technical Constraint : PLANTYPE-NTRL-2015_S-DB

Approvals



**Colours may not reproduce accurately on this proof.
You should refer to Pantone references for accurate colour match.**

Nature du changement/Reason for change:
- regulatory text:
New sentence added to the 'How to take' section of leaflet.