

Package leaflet: Information for the user
Telfast® Allergy 120mg film-coated tablets
fexofenadine hydrochloride

SANOFI 

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 an antihistamine. Telfast Allergy 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 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.

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. The 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.

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 as prescribed by your doctor.

If you stop taking Telfast Allergy

Tell your doctor if you want to stop taking Telfast Allergy before you have finished your course of treatment.

If you stop taking Telfast Allergy 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 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.

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

Telfast Allergy is presented in PVC/PE/PVDC/Al or PVC/PVDC/Al blister packs packaged into cardboard boxes. Telfast Allergy 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:

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Manufacturer

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30-36 Avenue Gustave Eiffel,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Allegra

Ireland: Telfast Allergy 120mg film-coated tablets

Malta: Allegratab 120mg film-coated tablets

This leaflet was last revised in July 2020.



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For Sanofi use only

Plant PM code : **751567**
Update : V5 - 16/JUL/2020
Local code : N.A.
Old PM code : CREATION
Name : **NT TELFAST ALLERGY
120MG RL**
Country : **IE**
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 (Portrait)
Plant barcode : *751567*
Colors : 1
- **BLACK**
Fonts : OceanSansPro SAN - L39HrP24Dh
Size mini : 10 Pts
Assembly Card : N.A.
Layout of Cutting : TN_LCG_NTRL_13c
Technical Constraint : PLANTYPE-NTRL-2015_S-DB (CAB/Verso ext.)

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:
- C - Marketing Change (new product launch, new design,
new presentation, new formula, ...)
- Creation of artworks for new product

751567 - NT.TELFAST ALLERGY 120MG RL IE

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IE
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Market health authorities approval	Joanne Clarke (Ireland regulatory team)	07/08/2020 14:15:25
Plant final technical validation	Beatrice Vallee-Duchet (Tours packaging team)	28/09/2020 11:30:00