

PACKAGE LEAFLET: INFORMATION FOR THE USER

Telfast® 180 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 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. Further Information

1. WHAT TELFAST IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Antihistamines for systemic use (R: Respiratory system) - ATC code: R06AX26.

This medicine is a histamine H1-receptor antagonist. It is used to treat itching that occurs with hives

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TELFAST

Contraindications:

Do not take Telfast in the following cases:

- in children less than 12 years of age due to the lack of safety and efficacy data,
- if you have a history of allergy to any of the ingredients of this medicine.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Appropriate precautions for use; special warnings:

Warnings and precautions

Talk to your doctor or pharmacist before taking Telfast.

Take special care with Telfast:

- if you are elderly,
- if you have liver or kidney problems,
- if you currently have heart problems or have had heart problems in the past, as this medicine can cause rapid or irregular heartbeat.

Other medicines and Telfast

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

If you are taking antacid medication containing aluminum hydroxide or magnesium hydroxide (used to relieve heartburn and acid reflux), you must allow an interval of at least 2 hours between taking that medication and Telfast.

No drug interactions have been observed with omeprazole. Also tell your doctor if you are currently taking medicines to treat:

- an infection caused by certain types of bacteria (erythromycin),
- an infection caused by certain microscopic fungi (ketoconazole).

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 this medicine during pregnancy unless you are advised to do so by your doctor.

If you discover that you are pregnant during treatment, talk to your doctor. Only your doctor will be able to decide whether it is necessary to continue treatment.

It is unclear as to whether this medicine is excreted in breast milk. It is not recommended for breast-feeding women.

Driving and using machines

Telfast does not cause any effects which could impair your ability to drive or use machines.

However, before driving or performing tasks requiring your full concentration, make sure that you have not developed an unusual response to this medicine and that taking this medicine does not affect your alertness.

Telfast contains microcrystalline cellulose, pregelatinized maize starch, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 400, titanium dioxide, colloidal anhydrous silica, povidone, yellow iron oxide and red iron oxide.

3. HOW TO TAKE TELFAST

Dosage

This medicine is for adults and children aged over 12 years only.

The dose is 1 tablet per day.

Method and route of administration

This medicine should be taken by mouth.

Duration of treatment

Follow your doctor's prescription.

If you take more Telfast than you should:

Contact your doctor or pharmacist immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following effects may occur:

- Nervous system disorders:
common (>1/100, <1/10): headache, drowsiness, dizziness
- Gastrointestinal disorders
common (>1/100, <1/10): nausea
not known: dry mouth
- General disorders:
uncommon (>1/1000, <1/100): fatigue

The following side effects have been reported in adults during post-marketing surveillance. The frequency is not known and cannot be estimated from the available data.

- Immune system disorders:
Allergic reactions including sudden swelling of the face and neck (angioedema), chest tightness, difficulty breathing (dyspnea), flushing and other systemic anaphylactic reactions have been reported.
- Psychiatric disorders:
Difficulty sleeping (insomnia), nervousness, sleep disorders or nightmares/excessive dreaming (paroniria)
- Cardiac disorders:
Accelerated heartbeat (tachycardia) or irregular heartbeat (palpitations).
- Gastrointestinal disorders:
Diarrhea.
- Skin and subcutaneous tissue disorders:
Transient development of spots (rash), red itchy patches on the skin (urticaria), itching (pruritus).

Uncommonly, headache has been reported in children, with a comparable frequency to that observed with placebo.

Reporting of side effects

If you get any side effects, talk to your doctor, your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. 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 outer packaging.

This medicinal product must be stored protected from moisture and at a temperature no higher than 30°C.

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. FURTHER INFORMATION

What Telfast 180 mg film-coated tablets contain

The active substance is:

Fexofenadine hydrochloride 180.00 mg
For one film-coated tablet.

The other ingredients are:

Microcrystalline cellulose, pregelatinized maize starch, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 400, titanium dioxide, colloidal anhydrous silica, povidone, yellow iron oxide, red iron oxide

What Telfast looks like and contents of the pack

This medicine is supplied as film-coated tablets; box of 15 or 30 film-coated tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorization Holder

sanofi-aventis France
82, avenue Raspail
94250 Gentilly - France

Manufacturer

Sanofi Winthrop Industrie
30-36, avenue Gustave Eiffel
37100 Tours - France

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