

# Telfast® 180 mg, film-coated tablets

fexofenadine hydrochloride



**This leaflet answers some common questions about Telfast. Please read the information carefully before taking Telfast.**

- This leaflet provides a summary of the information available. It does not contain all the available information.
- It does not take the place of talking to your pharmacist or doctor, who have more detailed information.
- If you have any questions about taking this medicine, or if you experience any problems while taking Telfast, speak to your pharmacist or doctor.
- All medicines have benefits and risks, so please discuss these with your pharmacist or doctor to make sure that the benefits of taking Telfast outweigh any possible risks.
- Keep this leaflet with the medicine as you may want to read it again.

## **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. While you are taking Telfast
5. Possible side effects
6. How to store Telfast
7. Further information

## **1. WHAT TELFAST IS AND WHAT IT IS USED FOR**

Telfast contains an active ingredient called fexofenadine hydrochloride. It is one of a group of medicines called antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, which your body produces when exposed to certain substances.

Telfast is a non-sedating antihistamine which means it has been shown not to cause drowsiness.

Telfast 180 mg tablets are used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes and itchy, blocked or runny nose as well as the symptoms of urticaria otherwise known as hives or itchy rash in adults and children aged 12 years or older.

Your pharmacist or doctor may have recommended this medicine for another reason.

Ask your pharmacist or doctor if you have any questions about why this medicine has been recommended for you.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TELFAST

### **Contraindications:**

#### **When you must not take it**

Do not take Telfast if you are pregnant, intend to become pregnant, or if you are breastfeeding, unless advised to do so by a Doctor or Pharmacist.

Do not take Telfast if you have had an allergic reaction allergy to fexofenadine, terfenadine or any of the other ingredients in Telfast. These are listed at the end of this leaflet.

Do not give Telfast to children under 12 years of age.

Do not take Telfast after the expiry date (EXP.) printed on the pack or if the packaging is damaged or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

### **Appropriate precautions for use; special warnings:**

#### **Before you start to take it**

You should inform your pharmacist or doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Your pharmacist or doctor will consider these points when recommending Telfast.

#### **Taking other medicines**

Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Telfast may interfere with each other.

Your pharmacist or doctor has more information on medicines to be careful with or to avoid while you are taking this medicine.

## 3. HOW TO TAKE TELFAST

### **How much to take**

For the relief of the symptoms of hayfever, the usual dosage for adults and children over 12 years of age is one Telfast 180 mg tablet daily, when required.

For relief of symptoms of hives or itchy rash, the usual dosage for adults and children over 12 years of age is one Telfast 180 mg tablet daily when required.

Talk to your pharmacist or doctor if you are unsure what dose to take.

The dosage directed by your pharmacist or doctor may be different to the recommended dose.

Do not take more than the dose your pharmacist or doctor has directed.

**How to take it**

Take Telfast with a glass of water or as directed by your pharmacist or doctor.

Telfast may be taken with or without food.

**How long to take it**

The duration of treatment depends on the type and duration of your complaint.

Talk to your pharmacist or doctor about how long to take Telfast.

If Telfast does not relieve your symptoms, do not take extra tablets. Tell your doctor or pharmacist.

**If you take too much (overdose)**

If you think that you or someone else may have taken too much Telfast immediately telephone your doctor or pharmacist, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

**4. WHILE YOU ARE TAKING TELFAST****Things you must do**

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Telfast.

If you are about to be started on any new medicine, tell your Doctor or Pharmacist that you are taking Telfast.

If you are to have surgery that needs a general anaesthetic, tell the doctor or dentist that you are taking this medicine.

If you become pregnant while taking Telfast, consult your Doctor or Pharmacist.

**Things you must not do**

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your pharmacist tells you to.

**5. POSSIBLE SIDE EFFECTS**

Tell your pharmacist or doctor as soon as possible if you do not feel well while taking Telfast, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

All medicines can cause side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Although most people will not experience any, some of the side effects that may occur with Telfast are:

- headache;
- tiredness;
- nausea;
- indigestion;
- dizziness;
- drowsiness.

These same effects were seen in patients taking “dummy” or placebo capsules during clinical studies.

Ask your pharmacist or doctor to answer any questions you may have.

### **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.

## **6. HOW TO STORE TELFAST**

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

### **Storage**

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep this medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink.

Do not leave it in the car, or on a windowsill.

Heat and damp can destroy some medicines.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

If your pharmacist or doctor tells you to stop taking Telfast, or if the product has passed its expiry date, ask your pharmacist what to do with any left over product.

## **7. FURTHER INFORMATION**

### **What Telfast, 180 mg film-coated tablet contains**

- The active substance is:  
fexofenadine hydrochloride..... 180 mg  
per tablet.

- The other ingredients are:  
microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate, povidone, titanium dioxide, colloidal anhydrous silica, macrogol 400, Pigment Blend Pink PB1254, Pigment Blend Yellow PB1255, hypromellose.

Telfast 180 mg does not contain any gluten, lactose or preservatives.

### **What Telfast, 180 mg film-coated tablet looks like and contents of the pack**

Telfast 180 mg are peach coloured and have a modified capsule shape.

Telfast 180 mg is available in 10, 15, 30, 50, 60 and 70 pack sizes.

Not all pack size may be marketed in your country.

**Marketing Authorization Holder**

sanofi-aventis Australia Pty Ltd  
12-24 Talavera Road  
Macquarie Park NSW 2113  
Australia

**Manufacturer**

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

**This leaflet was last approved in: January 2019.**

- **To report any side effect(s) :**
- **Saudi Arabia**

- **The National Pharmacovigilance Centre (NPC):**
  - Fax: +966-11-205-7662
  - Call NPC at +966-11-2038222, Ext 2317-2356-2340
  - SFDA Call Center: 19999
  - E-mail: [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)
  - Website: <https://ade.sFDA.gov.sa/>

- **Other GCC States:**
  - **Please contact the relevant competent authority.**

**This is a Medicament**

- **Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.**
- **The doctor and the pharmacist are the experts in medicines, their benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribed for you.**
- **Do not repeat the same prescription without consulting your doctor.**
- **Keep all medicaments out of reach of children.**

Council of Arab Health Ministers

Union of Arab Pharmacists

This patient information leaflet is approved by the Saudi Food and Drug Authority