PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription

Telfast® 180 mg,

Film Coated Tablets

SANOFI

Active ingredient and its amount:

Each tablet contains:

Fexofenadine hydrochloride 180 mg

Inactive ingredients: See section 6.

Read this leaflet carefully in its entirety before using the medicine.

- Keep this leaflet. You may need to read it again.
- This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
- Take the preparation according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if the symptoms of the illness worsen or are not improving after a few days.
- The medicine is not intended for children under 12 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is used for relief in cases of prolonged rash accompanied by itching.

Therapeutic group: Antihistamine.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

you are sensitive (allergic) to fexofenadine or to any of the other ingredients of the medicine (see section 6).

Special warnings regarding use of this medicine

Before taking Telfast, consult the doctor if:

- you suffer from impaired function of the kidney or liver.
- you suffer or have suffered in the past from heart disease, since this kind of medicine may lead to a fast or irregular heartbeat.
- you are elderly.

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

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking medicines for digestive problems that contain aluminium or magnesium which may affect the action of Telfast by lowering the amount of Telfast absorbed. It is recommended that you take these medicines two hours before or after taking Telfast.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with the doctor before using this medicine.

Do not take Telfast during pregnancy without instruction from a doctor.

Telfast is not recommended during breastfeeding.

Driving and operating machinery

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 SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the preparation.

For adults and children aged 12 years and over the recommended dosage is generally one tablet (180 mg) once a day. Swallow the medicine with water before a meal. There is no information regarding crushing or breaking the tablet.

Do not exceed the recommended dose.

If you accidentally took a higher dosage than you should

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room, and bring the package of the medicine with you. Symptoms of overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Telfast

If you forget to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time as recommended by the 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.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Telfast may cause side effects in some of the users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to your doctor immediately and stop taking Telfast if you suffer from swelling of the face, lips, tongue or throat, and difficulty breathing, as these may indicate that you suffer from a serious allergic reaction.

Common side effects (occurring in 1-10 in 100 users): headache, drowsiness, feeling sick (nausea) and dizziness.

Uncommon side effects (occurring in 1 user in 100): tiredness/sleepiness.

Additional side effects (frequency unknown) which may occur: difficulty sleeping (insomnia), sleeping disorders, bad dreams, nervousness, fast or irregular heartbeat, diarrhoea, skin rash and itching, hives, serious allergic reactions which may cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

5. HOW SHOULD TELFAST BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature below 30°C.

Do not throw any medicine in wastewater or a household waste. Ask your pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Tablet core: Microcrystalline Cellulose, Pregelatinised Maize Starch, Croscarmellose Sodium, Magnesium Stearate.
Film coating: Hypromellose, Macrogol 400, Titanium Dioxide, Colloidal Anhydrous Silica, Povidone, Yellow Iron Oxide Blend, Pink Iron Oxide Blend

How does the medicine look and what are the contents of the package

Telfast 180 mg film coated tablets are peach coloured, capsule shaped tablets marked with "018" on one side and "e" on the other.

Telfast 180 mg is marketed in blister packs. The package contains 2,10,15 tablets.

Not all package sizes are marketed.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask the doctor.

Manufacturer: Sanofi Winthrop Industrie, Tours, France.

License holder and its address: sanofi-aventis Israel ltd., P.O. Box 8090, Netanya.

Approved in December 2020

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 109 22 29136