

**PATIENT LEAFLET IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Telfast® 120 mg Film-Coated Tablets

Active ingredient

Each tablet contains fexofenadine hydrochloride 120 mg.

Inactive ingredients in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your doctor or pharmacist.

Take this preparation according to the instructions in the section about dose in this leaflet. Consult the pharmacist if you need further information. Contact the doctor if the disease symptoms get worse or do not improve after a few days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is used for relief of symptoms associated with seasonal allergic rhinitis.

Therapeutic group: Antihistamine.

2. BEFORE USING THIS 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 about using this medicine

Before starting treatment with Telfast, consult the doctor if:

- you suffer from impaired function of the kidneys 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 apply to you, or if you are not sure, tell your doctor before taking Telfast.

Children and adolescents

The medicine is not intended for children under the age of 12 years.

Interactions with other medicines

If you are taking, or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. In particular, if you are taking:

- apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.
- medicines for indigestion that contain aluminium or magnesium. These may affect the action of Telfast by lowering the amount of the medicine absorbed.

It is recommended that you take these medicines for indigestion two hours before or after taking Telfast.

Using this medicine and food

Swallow the medicine with water before a meal. Do not take with fruit juices.

Pregnancy and breastfeeding

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

Do not take Telfast during pregnancy, unless this is necessary.

Telfast is not recommended during breastfeeding.

Driving and using machines

Telfast is unlikely to affect your ability to drive or operate machinery; however, you should verify that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

For adults and children aged 12 years and over, the recommended dosage is generally one tablet (120 mg) once a day. Swallow the medicine with water before a meal. Do not take with fruit juices.

There is no information regarding crushing or breaking the tablet.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose

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

If you forget to take the medicine

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 this medicine

If you want to stop taking Telfast before finishing the course of treatment recommended by the doctor, tell the doctor.

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 every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Telfast may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact a 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.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo).

Common side effects (effects occurring in up to one in ten users):
headache, drowsiness, feeling sick (nausea), dizziness.

Uncommon side effects (effects occurring in up to one in 100 users):
tiredness/sleepiness.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
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, blurred vision.

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 your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE ?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature below 30°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Tablet core: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

Film-coating: macrogol 400, hydroxypropyl methylcellulose E-15, titanium dioxide (E171), hydroxypropyl methylcellulose E-5, colloidal anhydrous silica, povidone, yellow iron oxide blend, pink iron oxide blend.

What the medicine looks like and contents of the pack:

Film-coated, peach coloured, capsule shaped tablets marked with "012" on one side and "e" on the other.

Telfast 120 mg is marketed in blister packs. The package contains 2 or 15 tablets.

Not all pack sizes may be marketed.

Name and address of the license holder and importer: Pharmashalom Ltd., 21 Ha'Melacha St., Rosh-Ha'Ayin 4809157.

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Registration number of the medicine in the Ministry of Health National Drug Registry:
108 90 29135 21