

Patient Package Insert in Accordance with the Pharmacists'

Regulations (Preparations) – 1986

The medicine is dispensed without a doctor's prescription

Fexofenadine-Trima 120 mg

Film Coated Tablets

Fexofenadine-Trima 180 mg

Film Coated Tablets

Active ingredient and its amount:

Each tablet contains:	Each tablet contains:
fexofenadine hydrochloride 120 mg	fexofenadine hydrochloride 180 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 this leaflet carefully in its entirety before you start using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within a few days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Fexofenadine-Trima 120 mg: The medicine is used for relief of symptoms associated with seasonal allergic rhinitis.

Fexofenadine-Trima 180 mg: The medicine is used for relief of symptoms associated with persistent itchy rash (chronic idiopathic urticaria).

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 in this medicine (see section 6).

Special warnings about using this medicine

Before beginning treatment with Fexofenadine-Trima, 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 conditions apply to you, or if you are not sure, tell your doctor before you start taking Fexofenadine-Trima.

Children and adolescents

This medicine is not intended for children under 12 years old.

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-Trima may be decreased.

- medicines for indigestion that contain aluminium or magnesium. These may affect the action of Fexofenadine-Trima by lowering the amount of the medicine absorbed.

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

Using this medicine and food

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

Pregnancy and breastfeeding

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

Do not take Fexofenadine-Trima during pregnancy, unless this is necessary.

Fexofenadine-Trima is not recommended during breastfeeding.

Driving and operating machinery

Fexofenadine-Trima 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.

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 SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure about your dose and manner of treatment.

For adults and children aged 12 years and over, the recommended dosage is generally:

Fexofenadine-Trima 120 mg: one tablet (120 mg) once a day.

Fexofenadine-Trima 180 mg: one tablet (180 mg) once a day.

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

The tablets do not have a score-line. There is no information about breaking/crushing the tablets.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the medicine package with you. Symptoms of 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 scheduled time as recommended by the doctor.

If you stop taking this medicine

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

If you stop taking Fexofenadine-Trima earlier than planned, your symptoms may return.

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

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

4. SIDE EFFECTS

As with any medicine, using Fexofenadine-Trima may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Refer to a doctor immediately and stop taking Fexofenadine-Trima 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 side effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the medicine (placebo):

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

Uncommon side effects (effects occurring in up to 1 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 that may cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing, blurred vision.

If you experience any side effect, if any side effect worsens or if you experience a side effect not mentioned in the leaflet, you must consult with a doctor.

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

<https://sideeffects.health.gov.il>

You can also report side effects by email to: safety@trima.co.il.

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This medicine, and any other medicine, should be kept in a closed 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) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, magnesium stearate, Opadry OY 8704 Orange (hydroxypropylmethyl cellulose (HPMC), titanium dioxide, polyethylene glycol, FD&C yellow #6/Sunset Yellow fcf aluminium lake, D&C yellow #10 aluminium lake).

What the medicine looks like and contents of the pack:

Fexofenadine-Trima 120 mg - film coated, light orange, round, bi-convex tablets.

Fexofenadine-Trima 180 mg - film coated, light orange, oblong, bi-convex tablets.

Each pack contains 15 tablets packaged in blister trays.

Manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in September 2025.

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

Fexofenadine-Trima 120 mg: 162-12-35365-00

Fexofenadine-Trima 180 mg: 162-13-35366-00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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