

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) – 1986
The medicine is dispensed with a doctor's prescription only

Fexofenadine-Trima 120 mg Film Coated Tablets	Fexofenadine-Trima 180 mg Film Coated Tablets
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Active ingredient and its amount:

Each tablet contains: Fexofenadine hydrochloride 120 mg	Each tablet contains: Fexofenadine hydrochloride 180 mg
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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.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
- If any of the side effects worsens or if a side effect not mentioned in the leaflet occurs, please refer to the doctor or pharmacist.

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 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 to fexofenadine or to any of the medicine's ingredients (see section 6).

Special warnings regarding use of this medicine

Before beginning treatment with Fexofenadine-Trima, 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.

Children and adolescents:

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

Other medicines and Fexofenadine-Trima / Drug interactions:

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 lower the amount of Fexofenadine-Trima absorbed. It is recommended that you take these medicines two hours before or after taking Fexofenadine-Trima.

Using this medicine and food:

Swallow this medicine with water before a meal.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult with the doctor before using medicines.

Do not take Fexofenadine-Trima if you are pregnant, unless 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.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

The dosage and manner of treatment will be determined by the doctor only.

For adults and children over 12 years of age the recommended dose is:

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.

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

Do not exceed the recommended dose.

If you accidentally take more Fexofenadine-Trima than you should

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, tiredness and dry mouth.

If you forget to take Fexofenadine-Trima

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 prescribed by the doctor.

If you stop taking Fexofenadine-Trima

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, use of Fexofenadine-Trima 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 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.

Common side effects (occurring in less than 1 in 10 but more than 1 in 100 patients): headache, drowsiness, nausea and dizziness.

Uncommon side effects (occurring in less than 1 in 100 but more than 1 in 1,000 patients): tiredness/sleepiness.

Additional side effects (frequency unknown) which may occur: difficulty falling asleep, 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 you experience any side effect, if any side effect gets worse or when you experience a side effect not mentioned in the leaflet, you must consult with the doctor.

Reporting side effects

If you experience any side effect, tell your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

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). You can also use this link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

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

5. HOW SHOULD FEXOFENADINE-TRIMA BE STORED?

– Avoid 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) appearing on the package. The expiry date refers to the last day of that month.

Store in a dry place below 25°C.

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 aluminum lake, D&C yellow #10 aluminum lake).

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

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.

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

to the doctor.

Manufacturer and marketing authorization holder:

Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in April 2019.

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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