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

The medicine is dispensed with a doctor's prescription only

Prasugrel - Trima 10 mg
Film-coated tablets

Active ingredient
Each film-coated tablet contains: prasugrel 10 mg

For information regarding inactive ingredients and allergens, see section 2 under "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Prasugrel - Trima 10 mg is not intended for children and adolescents under the age of 18, since no information is available regarding the efficacy and safety of this medicine in this age group.

1. What is the medicine intended for?

Prasugrel - Trima 10 mg in combination with acetylsalicylic acid is intended for prevention of atherothrombotic events in patients with acute coronary syndrome (unstable angina pectoris, acute myocardial infarction) who are undergoing primary or planned catheterization with or without a stent.

Therapeutic class: platelet aggregation inhibitors.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (see section 6). An allergic reaction may occur as a rash, itch, swelling of the face and lips or shortness of breath. If you experience any of these effects, inform your doctor immediately.
- You have active bleeding (such as bleeding from an ulcer in your digestive system).
- You have previously had a stroke or a transient ischemic attack (TIA).
- You have severe liver disease.

Special warnings regarding the use of the medicine
Before treatment with Prasugrel - Trima, inform the doctor if:
- You have an increased risk for bleeding, for example:
  - You are over 75 years old. Your doctor will prescribe a dose of 5 mg (half a tablet) per day for you, since there is a greater risk for bleeding in these patients.
  - You have recently been severely injured.
  - You have recently had an operation (including certain dental surgeries).
  - You have recently had bleeding or you have recurring bleeding in the stomach or the intestine (including a gastric ulcer or an intestinal polyp).
  - You weigh less than 60 kg. Your doctor will prescribe a dose of 5 mg (half a tablet) per day of **Prasugrel - Trima** for you.
  - You have a kidney disease or moderate liver function impairment.
  - You are taking additional medicines (see the section "Drug interactions").
  - You are planning to undergo surgery (including dental procedures) in the next seven days. Your doctor may instruct you to temporarily stop taking **Prasugrel - Trima** due to increased risk for bleeding.
- You have had an allergic reaction (hypersensitivity) to clopidogrel or to any other platelet aggregation inhibitor. If you have taken **Prasugrel - Trima** and have had an allergic reaction including rash, itch, swelling of the face and tongue or shortness of breath – contact your doctor **immediately.**

During treatment with Prasugrel - Trima:
- If you experience a side effect called thrombotic thrombocytopenic purpura (TTP), which includes fever and small bruises under the skin which look like small red dots, with or without unexplained extreme fatigue, confusion, yellowing of the skin or eyes – contact the doctor immediately! (See section 4 - "Side effects").

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:
- Clopidogrel (platelet aggregation inhibitor).
- Warfarin (anticoagulant medicine).
- Nonsteroidal anti-inflammatory agents for treating pain and fever (e.g.: ibuprofen, naproxen, etoricoxib).
  Taking these medicines concurrently with **Prasugrel - Trima** may increase your risk for bleeding.
- Inform the doctor if you are taking morphine or other medicines of the opioid group (for treatment of severe pain).

Additional medicines may be taken together with **Prasugrel - Trima** only if your doctor approved them for you.

Use of the medicine and food
Prasugrel - Trima may be taken with or without food.

Pregnancy and breastfeeding
If you are pregnant, breastfeeding, think you might be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.
Inform the doctor if you become pregnant or if you are planning to become pregnant while taking **Prasugrel - Trima.** You should take the medicine only after consulting with your doctor about the benefit of the medicine and the possible risks to the fetus.

Driving and operating machinery
Prasugrel - Trima will probably not affect your ability to drive or to operate machinery.

Important information about some of the ingredients of the medicine
Prasugrel - Trima contains lactose. If you have been told by your doctor that you have an intolerance to certain types of sugars, contact your doctor before taking **Prasugrel - Trima.**

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined only by the doctor.
Do not exceed the recommended dose.
Take the tablet at about the same time every day.
The tablet can be halved at the score line.
There is no information about crushing/chewing.
During treatment with this preparation, you should be under medical supervision.
If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately refer to a doctor or a hospital emergency room and bring the package of the medicine with you, as you or the child may have an increased risk for bleeding.
Do not induce vomiting without an explicit instruction from the doctor!
If you have forgotten to take this medicine at the required time, take a dose as soon as you remember. If you have forgotten to take the medicine for an entire day, take the next dose at the usual time the next day, but do not take two doses on the same day under any circumstances!
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist. If you stop taking the medicine too soon, you may be at a higher risk for a heart attack.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Prasugrel - Trima may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Tell the doctor as soon as possible if:
- You have the following symptoms:
  - Sudden numbness or weakness of the arm, leg or face – especially if the numbness is only on one side of the body.
  - Sudden confusion, difficulty speaking or understanding others.
  - Sudden difficulty in walking or loss of balance or co-ordination.
  - Sudden dizziness or a sudden severe headache for no known reason.

  All of these symptoms may indicate a stroke. A stroke is an uncommon side effect of **Prasugrel - Trima** in patients who have never experienced a stroke or transient ischemic attack (TIA).
- You notice the appearance of fever and bruises that may appear as small, red, round dots on the skin. This effect may be accompanied by unexplained extreme fatigue, confusion and yellowing of the skin or eyes (see section 2 – "Before using the medicine").
- You notice a rash, itch, swelling of the face, lips/tongue or shortness of breath. These symptoms may indicate a severe allergic reaction (see section 2 – "Before using the medicine").
- Inform the doctor immediately if you experience any of the following symptoms:
  - Blood in the urine.
  - Anal bleeding, blood in the stool or black stool.
  - You are experiencing uncontrolled bleeding, such as bleeding from a cut or a wound.

  These symptoms may indicate bleeding, which is the most common side effect of using **Prasugrel - Trima**. Severe bleeding, on the other hand, occurs rarely, but is life-threatening.

Common side effects - side effects that occur in 1-10 out of 100 users:
- Gastric or intestinal bleeding.
- Bleeding from an injection site.
- Nose bleeds.
- Skin rash.
- Appearance of bruises on the skin, especially small red bruises (ecchymoses).
- Blood in the urine.
- Hematomas (bleeding under the skin at an injection site or bleeding into a muscle that causes swelling).
- Low levels of hemoglobin or low red blood cells count in the blood (anemia).
- Bruises.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- An allergic reaction (rash, itching, swelling of the lips or tongue, shortness of breath).
- Spontaneous bleeding from the eye, anus, gums or stomach (around internal organs).
- Post-operative bleeding.
- Coughing blood.
- Bloody stool.

Rare side effects - side effects that occur in 1-10 out of 10,000 users:
- Low level of platelets in a blood test.
- Subcutaneous hematomas (bleeding under the skin that causes swelling).

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

Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il
You can also report to the email: safety@trima.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from 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 below 25°C.**
- Do not discard medicines in the wastewater or a domestic trash can. Ask the pharmacist how to dispose of medicines no longer in use - this will help to protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Tablet core: lactose, hydroxypropyl cellulose, croscarmellose sodium, glycerol dibehenate, sodium laurilsulfate.

Tablet coating: polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171), glycerol monocaprylocaprate (type 1), sodium laurilsulfate, iron oxide yellow (E172).

What does the medicine look like and what are the contents of the package:
A round, yellow, biconvex film-coated tablet. The tablet is debossed with B23 on one side and is scored on the other side.
Pack sizes: 14, 28, 30, 56, 60, 90 film-coated tablets packed in blisters.
Not all pack sizes may be marketed.

Marketing authorization holder's name and address: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Name and address of the manufacturer: Gedeon Richter 99-105 Cuza Voda Street, 540306, Targu-Mures, Romania.

Revised in August 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: **173-37-36447-99**

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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