

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Dispensing this medicine requires a doctor's prescription

Eletriptan-Trima 40 mg Eletriptan-Trima 80 mg Film-coated tablets

Each coated tablet contains:

Eletriptan (as hydrobromide salt) 40 mg, 80 mg

For the list of inactive ingredients in this medicine, see section 6.

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

This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

This medicine is intended for adults over the age of 18 and under the age of 65.

For information on side effects, please see section 4.

1. What is this medicine intended for?

- For acute treatment at the headache stage of the migraine attack with or without an aura (which can be manifested by vision problems, dulled senses and speech disturbances).

Therapeutic group:

Selective agonist of the vascular (5HT_{1B}) and neuronal (5HT_{1D}) serotonin receptors. Serotonin is a natural substance found in the brain that helps to narrow the blood vessels.

2. Before using this medicine

X Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.
- You have or have ever had impaired function of your heart and/or blood vessels.
- You have or have ever had severely impaired function of your liver or kidney.
- You have or have ever had moderate to severe high blood pressure or mild untreated high blood pressure.
- You have or have ever had a stroke.
- You are being concomitantly treated with the following medicines: ketoconazole, itraconazole (for treating fungal infections), erythromycin, clarithromycin, josamycin (antibiotics), ritonavir, indinavir, nelfinavir (for treating AIDS), and other 5HT₁, serotonin receptor agonists (for treating migraine).
- Do not take medicines from the ergot group (for treating migraine) within 24 hours before or after taking Eletriptan-Trima.
- You have a rare hereditary problem of intolerance to galactose, Lapp lactase deficiency, or impaired absorption of glucose or galactose.

▲ Special warnings about using this medicine:

Do not use this medicine before consulting a doctor:

- if you have, or have ever had diabetes.
- if you smoke or are being treated with nicotine replacement products.

- if you have or have ever had impaired function of your kidney/urinary tract.
- if you are male and over 40 years.
- if you are female and post-menopausal.
- if you have or know of a family history of coronary artery disease.
- if you are at increased risk of heart disease.
- if you have, or have ever had high blood pressure.
- if you have daily long-term headaches associated with migraine treatment.

▲ If you are sensitive to any food or medicine, inform your doctor before taking the medicine.

▲ If you are sensitive to lactose. This medicine contains lactose and may cause allergic reaction in people who are sensitive to lactose.

▲ This medicine contains the substance Sunset Yellow (FD&C yellow No.6) which may cause allergic reactions.

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

- The plant St. John's wort and medicines with serotonergic activity (such as medicines from the SSRI and/or SNRI groups) for treating depression - the combination may increase the risk of developing serotonin syndrome.
- Do not take this medicine if you are being concomitantly treated with: ketoconazole, itraconazole (for treating fungal infections); erythromycin, clarithromycin, josamycin (antibiotics); ritonavir, indinavir, nelfinavir (for treating AIDS); and other 5HT₁, serotonin receptor agonists (for treating migraine).
- Do not take medicines from the ergot group (for treating migraine) within 24 hours before or after taking Eletriptan-Trima.

Using the medicine and food

This medicine can be taken with or without food. Swallow the tablet with a glass of water.

Pregnancy and breastfeeding

Do not use the medicine without consulting a doctor before commencing the treatment if you are pregnant or breastfeeding, think you might be pregnant or planning to become pregnant or breastfeed.

It is recommended to avoid breastfeeding for 24 hours after taking this medicine.

Driving and using machines

Eletriptan or the migraine itself may make you sleepy. This medicine can also make you feel dizzy. Therefore avoid driving and using machines during a migraine attack or after taking this medicine.

3. How to use this medicine?

Always use according to the doctor's instructions!

The dosage and treatment regimen will be determined by the doctor only. This medicine is intended for adults over the age of 18 and under the age of 65.

This medicine can be taken at any stage after the migraine pain appears, but it is best to do so as soon as possible. **In any case, only take Eletriptan-Trima during the headache phase of your migraine. Do not take this medicine as a preventive treatment for migraine attacks.**

- The usual starting dose is one 40 mg tablet.
- If the first tablet does not relieve your migraine, do not take a second tablet for the same attack.

- If after a first tablet your migraine is relieved and then comes back, you may take a second tablet. However, you must wait at least 2 hours before taking the second tablet.
- If one 40 mg tablet does not relieve your migraine, tell your doctor, and he or she decide to increase the dose.

Complete the treatment recommended by the doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not exceed the recommended dose!

In the absence of score line the tablet must not be halved. There is no information regarding crushing/chewing the tablets.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you. Side effects from taking an overdose include: a rise in blood pressure, and heart problems.

Persist with the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the 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

Like all medicines, taking this medicine 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.

Stop treatment and consult your doctor immediately in the event of:

- An allergic reaction: breathing difficulties, wheezing, swelling around the eyelids, face, and lips, widespread rash and itching (over the whole body).
- Rapid heart rate, restlessness, hallucinations, loss of coordination, increased body temperature, sharp changes in blood pressure, and overactive reflexes - symptoms of serotonin syndrome.
- Severe pains or tightness in the chest or throat - these are symptoms of a problem of the blood circulation of the heart (ischemic heart disease).

Other common side effects (appear in 1-10 out of 100 users):

Chest pain or tightness, heart palpitations, rapid heart rate, feeling sleepy, headache, dizziness, spinning sensation (vertigo), reduced sense of touch or pain, numbness, sore throat or throat tightness, dry mouth, abdominal pain, indigestion (dyspepsia), nausea, increased muscle tone (stiffness), muscle weakness, back pain, muscle pain, weakness, pain, feeling hot or flushing, chills, sweating, tingling, pharyngitis, runny nose.

Other uncommon side effects (appear in 1-10 out of 1000 users):

Difficulty breathing, yawning, swelling of the face or hands and legs, inflammation or infection of the tongue, skin rash, itching, oversensitivity to touch or pain, loss of coordination, difficult or slowed movement, tremors, speech disturbance, not feeling oneself (depersonalization), depression, abnormal thoughts, agitation, confusion, mood swings (euphoria), unresponsiveness, feeling of discomfort or illness (malaise), insomnia, loss of appetite and weight loss (anorexia), disturbed sense of taste, thirst, joint pain, degenerating joints, bone pain, increased need to urinate, passing excessive quantity of urine, impaired urinary system function, diarrhea, blurred vision, eye pain, intolerance to light, dry or watery eyes, pain or ringing in the ears, poor circulation.

Other rare side effects (appear in 1-10 out of 10,000 users):

Shock, asthma, hives (urticaria), skin disorders, swollen tongue, respiratory tract infection, enlarged lymph glands, slow heart rate,

emotional instability (mood swings), degeneration of joints (arthritis), spasms, myopathy (muscle disease), constipation, inflamed gullet, belching, breast pain, heavy or prolonged menstrual bleeding, eye infection (conjunctivitis), voice change, increased blood bilirubin levels and changes in liver enzymes in blood tests.

Side effects of an unknown frequency:

Vomiting, increased blood pressure, fainting, ischemic colitis, myocardial ischemia, myocardial infarction, narrowing of the coronary artery, cerebrovascular accident (stroke).

If any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects, or by clicking the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

Side effects can also be reported by email to safety@trima.co.il

5. How to store the medicine?

Store in a dry place below 25°C

Avoid poisoning! This medicine and any other medicines should be kept in a closed place out of reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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.

6. Additional information

In addition to the active ingredient this medicine also contains: Lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, methocel E5 (HPMC), titanium dioxide, polyethylene glycol 400, FD&C yellow No.6 aluminum lake, D&C yellow No.10 aluminum lake.

This medicine contains lactose and sodium:

Eletriptan-Trima 40 mg: Each tablet contains: about 0.27 mg sodium and 106.34 mg lactose.

Eletriptan-Trima 80 mg: Each tablet contains: about 0.54 mg sodium and 212.68 mg lactose.

What the medicine looks like and what are the contents of the package?

Eletriptan-Trima 40 mg: orange, round, bi-convex, film-coated tablets.

Eletriptan-Trima 80 mg: orange, round, bi-convex, film-coated tablets.

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

This leaflet was reviewed and approved by the Ministry of Health in: July 2017.

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

Eletriptan-Trima 40 mg: 159.03.34741.00

Eletriptan-Trima 80 mg: 159.04.34755.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.



0817A