Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only.

Rasagiline-Trima
Tablets

Active ingredient
Each tablet contains:
rasagiline (as mesylate) 1 mg

For the list of inactive ingredients in the preparation, see section 6 – "Additional information".

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

This medicine has been prescribed to treat your illness. 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.

1. What is this medicine intended for?

For the treatment of Parkinson's disease (PD) as monotherapy or as adjunct therapy with levodopa.

Therapeutic group:
Selective monoamine oxidase type B inhibitors.

With Parkinson's disease, there is damage to cells that produce dopamine in the brain. Dopamine is a chemical substance in the brain involved in movement control. Rasagiline-Trima helps to increase and sustain levels of dopamine in the brain.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (rasagiline) or to any of the other ingredients in the medicine (see section 6 – "Additional information").
- You are suffering from severe liver insufficiency.

Do not use Rasagiline-Trima concomitantly with the following medicines:
- pethidine (a strong pain killer).
- monoamine oxidase inhibitors (whether given as medicines for depression, for Parkinson's disease, or for any other indication, including natural or medicinal preparations given without a doctor's prescription, e.g., St. John's Wort for depression).

You must wait at least 14 days between stopping taking Rasagiline-Trima and starting treatment with monoamine oxidase inhibitors or with pethidine.

Special warnings about using this medicine
Before beginning treatment with Rasagiline-Trima, tell your doctor if:
- you are suffering from a liver problem.
- you noticed suspicious skin changes. Treatment with Rasagiline-Trima may increase the risk of skin cancer.

Notify the doctor if your family/caregiver notices that you are developing unusual behaviors, where you fail to resist an impulse, urge or desire to carry out actions that are harmful or destructive to yourself or others. This condition is defined as impulse control disorders. In patients taking rasagiline together with other medicines to treat Parkinson's disease, behavior disorders, such as compulsive behavior, obsessive thoughts, gambling addiction, excessive spending, impulse for abnormal behavior, increased sexual drive or increased sexual thoughts/excitement have been observed. Your doctor will consider adjusting the dosage or stopping the medicine (see section 4 – "Side effects").
Rasagiline-Trima may cause drowsiness and may cause you to suddenly fall asleep during day-time activities, especially if you are taking other dopaminergic medicines (used to treat Parkinson's disease). For further information, see "Driving and using machines" section.

Smoking
Inform the doctor or pharmacist if you smoke or plan to stop smoking. Smoking can reduce the levels of rasagiline in the blood.

Children and adolescents
The efficacy and safety of rasagiline in the pediatric and adolescent population have not been tested. There is no relevant use of the medicine for Parkinson's disease in children and adolescents. Therefore, Rasagiline-Trima is not intended for use under the age of 18 years.

Drug interactions
If you are taking, have recently taken or plan to take other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
In particular, if you are taking:
- antidepressants (e.g., tricyclics, tetracyclics, selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs]), monoamine oxidase inhibitors.
- ciprofloxacin (an antibiotic against infections).
- dextromethorphan (cough suppressant).
- sympathomimetics such as those present in eye drops, oral or nasal decongestants or cold medicines that contain ephedrine or pseudoephedrine.
- pethidine – see in section 2 – "Do not use this medicine".

Avoid using this medicine concomitantly with antidepressants that contain fluoxetine or fluvoxamine. Wait at least a period of 5 weeks between discontinuing treatment with fluoxetine and starting treatment with Rasagiline-Trima. On the other hand, if you are starting treatment with fluoxetine or fluvoxamine, do so at least 14 days after discontinuing treatment with Rasagiline-Trima.

Using this medicine and food
The medicine can be taken with or without food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, suspect that you are pregnant or are considering becoming pregnant, consult a doctor or pharmacist before using this medicine. You must avoid taking Rasagiline-Trima if you are pregnant, as the effects of Rasagiline-Trima on the pregnancy and on the fetus are unknown.

Driving and using machines
Consult with your doctor before you drive and operate machinery, since Parkinson's disease itself, as well as the treatment with Rasagiline-Trima, may influence your ability to do so. Rasagiline-Trima can cause dizziness or drowsiness and can also cause episodes of sudden sleep onset.
The effect can be increased if you take other medicines to treat the symptoms of your Parkinson's disease, or if you take medicines which can make you feel drowsy, or if you drink alcohol while taking Rasagiline-Trima.
If you have experienced drowsiness and/or episodes of sudden sleep onset in the past or while taking Rasagiline-Trima, do not drive or operate machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually one 1 mg tablet per day, with or without food.
Use this medicine at specified time intervals, as determined by the doctor.

Do not exceed the recommended dose
In the absence of a score line, do not halve the tablets. There is no information about crushing/chewing. Swallow the tablet whole, with water.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Rasagiline-Trima overdose can be manifested by the following symptoms: slightly euphoric mood (minor form of mania), very high blood pressure and serotonin syndrome (see section 4 – "Side effects").

If you forget to take the medicine at the scheduled time, do not take two doses together to compensate for the forgotten dose. Take the next dose at the usual time.
Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop treatment with Rasagiline-Trima without consulting your doctor.

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

4. Side effects

As with any medicine, using Rasagiline-Trima 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 the doctor immediately if:
- you develop unusual behaviors such as compulsive behavior, obsessive thoughts, gambling addiction, excessive spending or shopping, impulsive behavior and an abnormally increased sex drive or increased sexual thoughts (impulse control disorders) (see section 2 – "Before using this medicine").
- you see or hear things that do not exist (hallucinations).
- in any combination of hallucinations, fever, restlessness, tremor or sweating (serotonin syndrome).

Contact your doctor if you notice suspicious skin changes because there may be an increased risk of skin cancer (melanoma) with the use of this medicine (see section 2 – "Before using this medicine").

Additional side effects
Very common side effects – effects that occur in more than 1 in 10 users:
- involuntary movements (dyskinesia)
- headache

Common side effects – effects that occur in 1-10 in 100 users:
- abdominal pain
- falling
- allergic reactions
- fever
- flu
- general unwell feeling
- neck pain
- chest pain (angina pectoris)
- low blood pressure upon transitioning from sitting to standing with symptoms such as dizziness
- anorexia (lack of appetite)
- constipation
- dry mouth
- nausea and vomiting
- flatulence
- abnormal blood test results (leucopenia - white blood cell deficiency)
- joint pain
- muscle pain
- joint inflammation (arthritis)
- numbness and weakness of the hand muscles (Carpal tunnel syndrome)
- weight loss
- abnormal dreams
- difficulty with muscle coordination (balance disturbance)
- depression
- dizziness (vertigo)
- prolonged muscle contractions (dystonia)
- runny nose (rhinitis)
- skin irritation (skin inflammation - dermatitis)
- rash
- red and swollen eyes (conjunctivitis)
- urinary urgency

Uncommon side effects – effects that occur in 1-10 in 1,000 users:
- stroke
- heart attack (myocardial infarction)
- a rash that appears in the form of blisters

Side effects of unknown frequency (it is not possible to know the frequency based on the available data)
- rise in blood pressure
- excessive drowsiness
- sudden onset of sleep

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your 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 links to 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! 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 a 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 below 25°C in the original package.
- 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. Additional information

In addition to the active ingredient, this medicine also contains:
Mannitol, maize starch, pregelatinized starch, stearic acid, colloidal silicon dioxide.

What the medicine looks like and the contents of the pack:
A white, biconvex, round tablet.
The package contains 10 or 30 tablets.
Not all pack sizes may be marketed.

Manufacturer's and License Holder's name and address:
Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in March 2023 according to MOH guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
155-62-34403-00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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