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

This medicine is dispensed with a doctor's prescription only

Rasagiline Sandoz® 1 mg
Tablets

Each tablet contains:
rasagiline (as rasagiline tartrate) 1 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and 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 illness is similar to yours.

1. What is this medicine intended for?

Rasagiline Sandoz is used for the treatment of Parkinson's disease in adults and can be used with or without Levodopa.

Therapeutic group:
Selective monoamine oxidase type B inhibitors.

With Parkinson's disease, there is a loss of cells that produce dopamine in the brain. Dopamine is a chemical in the brain involved in movement control. Rasagiline Sandoz 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 of this medicine (please see section 6, 'Additional information').
- You are suffering from severe liver insufficiency.

Do not take the following medicines while taking Rasagiline Sandoz:
- Pethidine (a strong pain killer)
- Monoamine oxidase inhibitors (whether given as medicine for depression, for Parkinson's disease, or for any other indication, including natural or medicinal products without prescription e.g. St. John's Wort for depression).

You must wait at least 14 days after stopping Rasagiline Sandoz treatment before starting treatment with MAO inhibitors or pethidine.

Special warnings regarding the use of the medicine
Talk to your doctor before taking Rasagiline Sandoz if:
- you have a liver problem
- you notice any suspicious skin changes. Rasagiline Sandoz treatment may increase the risk of skin cancer.

Tell your doctor if you or your family/carer notices that you are developing unusual behaviours where you cannot resist the impulse, urge, or cravings to carry out certain harmful or detrimental activities to yourself or others. This condition is defined as impulse control disorders.
In patients taking Rasagiline Sandoz together with other medications for Parkinson's disease, behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive spending, impulsive abnormal behaviour, an abnormally high sex drive, or an increase in sexual thoughts/feelings have been observed. Your doctor will consider adjusting your dosage or stopping your medicine (see section 4, 'Side Effects').
Rasagiline Sandoz may cause drowsiness and may cause you to suddenly fall asleep during day time activities, especially if you are taking other dopaminergic medicines (used for the treatment of Parkinson's disease). For further information, refer to the section 'Driving and using machines'.

Children and adolescents
The efficacy and safety of Rasagiline Sandoz in children and adolescents has not been tested. This medicine is not used to treat Parkinson's disease in children and adolescents. Therefore, Rasagiline Sandoz is not recommended for use under the age of 18 years.

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

Other medicines and Rasagiline Sandoz
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including non-prescription medications and dietary supplements.
In particular, inform your doctor if you are taking any of the following medicines:
- Antidepressants (e.g., tricyclic or tetracyclic antidepressants, selective serotonin reuptake inhibitors [SSRIs], selective serotonin-norepinephrine reuptake inhibitors [SNRIs])
- Ciprofloxacin (an antibiotic used against infections)
- Dextromethorphan (a cough suppressant)
- Sympathomimetics such as those present in eye drops, oral and nasal decongestants, and cold medicines containing ephedrine or pseudoephedrine
- Pethidine, monoamine oxidase inhibitors—see section 2, 'Do not use this medicine if'.

The use of this medicine together with antidepressants containing fluoxetine or fluvoxamine should be avoided. Wait a period of 5 weeks at least after stopping treatment with fluoxetine before starting treatment with Rasagiline Sandoz. However, if you are starting treatment with fluoxetine or fluvoxamine, first wait at least 14 days after stopping Rasagiline Sandoz treatment.

Pregnancy and breast-feeding
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- You should avoid taking Rasagiline Sandoz if you are pregnant, as the effects of Rasagiline Sandoz on pregnancy and the unborn child are not known.

Driving and using machines
Ask your doctor for advice before you drive and operate machines, since Parkinson's disease itself as well as the treatment with Rasagiline Sandoz may influence your ability to do so. Rasagiline Sandoz can make you feel dizzy or drowsy and it can also cause episodes of sudden sleep onset.
This effect might be enhanced 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 Sandoz.
If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking Rasagiline Sandoz do not drive or operate machines.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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 tablet of 1 mg once daily, with or without food. Take this medicine at regular times as prescribed by your doctor.

Do not exceed the recommended dose.

Crushing/splitting/chewing
Swallow the tablet whole with water.
There is no information about crushing the tablet.

If you have accidentally taken a higher dose, if you have taken 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 following overdose of Rasagiline Sandoz may be: slightly euphoric mood (minor form of mania), extremely high blood pressure, and serotonin syndrome (see section 4, 'Side Effects').

If you forget to take this medicine at the scheduled time, do not take a double dose to make up for the missed 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 taking Rasagiline Sandoz 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

Like all medicines, Rasagiline Sandoz 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 your doctor immediately if:
- You develop unusual behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive spending or shopping, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts (impulse control disorders) (see section 2, 'Before using this medicine').
- You see or hear things which are not there (hallucinations).
- you get any combination of hallucinations, fever, restlessness, tremor and sweating (serotonin syndrome).

Contact your doctor if you notice any suspicious skin changes because there is a higher risk of skin cancer (melanoma) in patients taking this medicine (see section 2, 'Before using this medicine').

Additional side effects
Very common side effects (affect more than 1 in 10 users):
• involuntary movements (dyskinesia) • headache

Common side effects (affect 1-10 in 100 users):
• abdominal pain • fall • allergic reactions • fever • flu • general feeling of being unwell (malaise) • neck pain • chest pain (angina pectoris) • low blood pressure when rising from sitting to a standing position with symptoms like dizziness/light-headedness (orthostatic hypotension) • anorexia (loss of appetite) • constipation • dry mouth • nausea and vomiting • flatulence • abnormal results of blood tests (leucopenia - reduced number of white blood cells) • joint pain • muscle pain • joint inflammation (arthritis) • numbness and muscle weakness of the hand (carpal tunnel syndrome) • decreased weight • abnormal dreams • difficulty in muscular coordination (balance disorder) • depression • dizziness (vertigo) • prolonged muscle contractions (dystonia) • runny nose (rhinitis) • irritation of the skin (dermatitis) • rash • bloodshot, swollen eyes (conjunctivitis) • urinary urgency

Uncommon side effects (affect 1-10 in 1000 users):
• stroke (cerebrovascular accident) • heart attack (myocardial infarction) • a rash that appears in the form of blisters

Side effects of unknown frequency (the frequency of these effects has not been established yet):
• elevated 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

5. How to store the medicine?

Avoid 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.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

Storage conditions:
Store below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:
cellulose microcrystalline, starch pregelatinised (from maize), maize starch, talc, sodium stearyl fumarate.

What the medicine looks like and contents of the pack
Rasagiline Sandoz 1 mg: white to off-white, round, flat, bevelled tablets.
Bottle packs contain 10 or 30 tablets.
Blister tray packs contain 30 tablets.
Not all pack sizes may be marketed.

Registration holder and importer's name and address:
Novartis Israel Ltd., POB 7126, Tel Aviv.

Revised in March 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Rasagiline Sandoz 1 mg tablets: 169-02-36068-00