

**Package leaflet: Information for the patient****Rasagiline 1 mg tablets**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

**1. What this medicine is and what it is used for**

This medicine contains active ingredient called Rasagiline, and it is used for the treatment of Parkinson's disease. It can be used together with or without Levodopa (another medicine that is used to treat Parkinson's disease).

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. This medicine helps to increase and sustain levels of dopamine in the brain.

**2. What you need to know before you take this medicine****Do not take this medicine:**

- if you are allergic to rasagiline or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver problems

**Do not take the following medicines while taking this medicine:**

- monoamine oxidase (MAO) inhibitors (e.g. for treatment of depression or Parkinson's disease, or used for any other indication), including medicinal and natural products without prescription e.g. St. John's Wort.
- pethidine (a strong pain killer).

You must wait at least 14 days after stopping treatment with this medicine and starting treatment with MAO inhibitors or pethidine.

**Warnings and precautions**

Talk to your doctor, before taking this medicine:

- if you have any liver problems

You should speak with your doctor about any suspicious skin changes.

Tell your doctor if you or your family/carer notices that you are developing unusual behaviours where you cannot resist the impulse, urges or cravings to carry out certain harmful or detrimental activities to yourself or others. These are called impulse control disorders. In patients taking this medicine and/or other medicine used to treat Parkinson's disease, behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts or feelings have been observed. Your doctor may need to adjust or stop your dose (see section 4).

Rasagiline may cause drowsiness and may cause you to suddenly fall asleep during day time activities, especially if you are taking other dopaminergic medicinal products (used for the treatment of Parkinson's disease). For further information please refer to section driving and using machines.

**Children and adolescents**

There is no relevant use of rasagiline in children and adolescents. Therefore, rasagiline is not recommended for use under the age of 18.

**Other medicines and Rasagiline**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor if you are taking any of the following medicines:

- Certain antidepressants (selective serotonin reuptake inhibitors, selective serotonin norepinephrine reuptake inhibitors, tricyclic or tetracyclic antidepressants)
- The antibiotic ciprofloxacin used against infections
- The cough suppressant dextromethorphan
- Sympathomimetics such as those present in eye drops, nasal and oral decongestants and cold medicine containing ephedrine or pseudoephedrine

The use of rasagiline together with the antidepressants containing fluoxetine or fluvoxamine should be avoided

If you are starting treatment with rasagiline, you should wait at least 5 weeks after stopping fluoxetine treatment.

If you are starting treatment with fluoxetine or fluvoxamine, you should wait at least 14 days after stopping rasagiline treatment.

Tell your doctor or pharmacist if you are smoking or intend to stop smoking. Smoking could decrease the amount of rasagiline in the blood.

**Pregnancy, breast-feeding and fertility**

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 if you are pregnant, as the effects of rasagiline 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 may influence your ability to do so. Rasagiline can make you feel dizzy or drowsy; it can also cause episodes of sudden sleep onset.

This 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. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking rasagiline do not drive or operate machinery (see section 2).

**3. How to take this medicine**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one tablet of one mg taken by mouth once daily.
- Swallow the tablet whole with a drink of water.
- This medicine may be taken with or without food.

**If you take more of this medicine than you should**

If you think that you may have taken too many rasagiline tablets, contact your doctor or pharmacist immediately. Take the rasagiline carton/ blister or bottle with you to show the doctor or pharmacist.

Symptoms reported following overdose of rasagiline included slightly euphoric mood (light form of mania), extremely high blood pressure and serotonin syndrome (see section 4).

**If you forget to take this medicine**

If you forget to take a dose, just take your next dose as normal.

Do not take a double dose to make up for a forgotten dose.

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**If you stop taking this medicine**

Do not stop taking rasagiline unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor right away** if you notice any of the following symptoms. You may need urgent medical advice or treatment:

- If you develop unusual behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive shopping or spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts (impulse control disorders) (see section 2).
- If you see or hear things which are not there (hallucinations).
- Any combination of hallucinations, fever, restlessness, tremor and sweating (serotonin syndrome)
- If you notice any suspicious skin changes because there is a higher risk of skin cancer (not exclusively melanoma) in patients with Parkinson's disease (see section 2).

**Other side effects:****Very common (may affect more than 1 in 10 people)**

- involuntary movements (dyskinesia)
- headache

**Common (may affect up to 1 to 10 people)**

- abdominal pain
- fall
- allergy
- fever
- flu (influenza)
- neck pain
- general feeling of being unwell (malaise)
- decreased appetite
- constipation
- dry mouth
- nausea and vomiting
- joint pain (arthralgia)
- musculoskeletal pain
- decreased weight
- abnormal dreams
- depression
- dizziness (vertigo)
- flatulence
- prolonged muscle contractions (dystonia)
- runny nose (rhinitis)
- irritation of the skin (dermatitis)
- rash
- bloodshot eyes (conjunctivitis)
- urinary urgency
- abnormal results of blood tests (leucopenia)
- joint inflammation (arthritis)
- chest pain (angina pectoris)
- numbness and muscle weakness of the hand (carpal tunnel syndrome)
- difficulty in muscular coordination (balance disorder)
- low blood pressure when rising to a standing position with symptoms like dizziness light-headedness (orthostatic hypotension)

**Uncommon (may affect up to 1 in 100 people)**

- stroke (cerebrovascular accident)
- heart attack (myocardial infarction)
- blistering rash (vesiculobullous rash)

**Not known (frequency cannot be estimated from the available data)**

- elevated blood pressure
- excessive drowsiness
- sudden onset of sleep

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the YellowCard Scheme at- [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store this medicine**

- Keep this medicine out of the sight and reach of children.
- For blisters: Do not store above 30°C. Store in the original package in order to protect from light.  
For bottles: Do not store above 30°C. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What this medicine contains**

- The active substance is rasagiline. Each tablet contains 1 mg of rasagiline (as hemitartrate).
- The other ingredients are microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate.

**What this medicine looks like and contents of the pack**

- These tablets are white to off white round, flat with bevelled edges and debossed "1" on one side.
- This medicine is available in blister packs of 7, 10, 28, 30, 100 or 112 tablets and bottle packs of 30 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Rasagiline 1 mg tablets: PL 17907/0538**

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.