

Package leaflet: Information for the user**Rasagiline Rivopharm 1 mg tablets
Rasagiline**

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

Pharmacode

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

1. What Rasagiline tablets is and what it is used for

The full name of your medicine is "Rasagiline Rivopharm 1 mg tablets". It is referred to as "Rasagiline tablets" in the rest of the leaflet. Rasagiline tablets 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. Rasagiline tablets helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take Rasagiline tablets**Do not take Rasagiline tablets:**

- if you are allergic (hypersensitive) 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 Rasagiline tablets:

- 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.
 - pethidine (a strong pain killer).
- You must wait at least 14 days after stopping Rasagiline tablets treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions Rasagiline tablets

Talk to your doctor or pharmacist before taking Rasagiline tablets if you have any liver problems

You should speak with your doctor about any suspicious skin changes. Treatment with Rasagiline tablets may possibly increase the risk of skin cancer.

Children and adolescents

Rasagiline tablets is not recommended for use under the age of 18.

Other medicines and Rasagiline tablets

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-nor epinephrine 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 tablets together with the antidepressants containing fluoxetine or fluvoxamine should be avoided. If you are starting treatment with Rasagiline tablets, 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 tablets treatment.

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

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 Rasagiline tablets and/or other medications 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 tablets 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.

Rasagiline tablets with food, drink and alcohol

Rasagiline tablets may be taken with or without food.

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.

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 tablets may influence your ability to do so. Rasagiline tablets 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 tablets. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking Rasagiline tablets do not drive or operate machinery (see section 2).

3. How to take Rasagiline tablets

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 usual dose of Rasagiline tablets is 1 tablet of 1 mg taken by mouth once daily.

Rasagiline tablets may be taken with or without food.

If you take more Rasagiline tablets than you should

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

If you forget to take Rasagiline tablets

Do not take a double dose to make up for a forgotten dose. Take the next dose normally, when it is time to take it.

If you stop taking Rasagiline tablets

Do not stop taking Rasagiline tablets without first talking to your doctor.

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

4. Possible side effects

Like all medicines, Rasagiline tablets 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)

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

Other side effects

Very common (may affect more than 1 in 10 people)

- involuntary movements (dyskinesia)
- headache

Common (may affect up to 1 in 10 people)

- abdominal pain
- fall
- allergy
- fever
- flu (influenza) (pancreatitis),
- general feeling of being unwell (malaise)
- neck pain
- chest pain (angina pectoris)
- low blood pressure when rising to a standing position with symptoms like dizziness/light-headedness (orthostatic hypotension)
- decreased appetite
- constipation
- dry mouth
- nausea and vomiting
- flatulence
- abnormal results of blood tests (leucopenia)
- joint pain (arthralgia)
- musculoskeletal 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 eyes (conjunctivitis)
- urinary urgency

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rasagiline tablets

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

For blisters: 'This medicinal product does not require any special temperature storage conditions. Store in the original immediate package to protect from light.'

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 Rasagiline tablets contains**

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

What Rasagiline tablets looks like and contents of the pack

Rasagiline tablets are presented white to off white round, flat tablets with bevelled edges and engraved with "1" in one side, with a diameter of 8 mm.

The tablets are available in blister packs of 28 tablets.

Marketing Authorisation Holder

Rivopharm UK Ltd
30th Floor
40 Bank Street
Canary Wharf
London, E14 5NR
United Kingdom

Manufacturer

Genepharm S.A.
18 km Marathon Avenue
153 51 Pallini
Greece

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 **Rivopharm**