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Package leaflet: Information for the user

Rasagiline 1 mg tablets

Rasagiline

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

1 What Rasagiline is and what it is used for

Rasagiline contains the active substance rasagiline and it is used for the treatment of Parkinson's disease in adults. 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 helps to increase and sustain levels of dopamine in the brain.

2 What you need to know before you take Rasagiline

Do not take Rasagiline:
- 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 Rasagiline:
- 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 Rasagiline treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions
Talk to your doctor before taking Rasagiline.
- If you have any liver problems
- You should speak with your doctor about any suspicious skin changes.
- If you are taking buprenorphine-containing medicinal products. The use of these medicines together with Rasagiline can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Rasagiline").

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 and/or other medicines 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

Some medicines may increase the side effects of Rasagiline and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Rasagiline without first talking to your doctor, especially:

- Buprenorphine-containing medical products. These medicines may interact with Rasagiline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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 Rasagiline

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

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The recommended dose of Rasagiline is 1 tablet of 1 mg taken by mouth once daily. Rasagiline may be taken with or without food.

If you take more Rasagiline 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 box/ blister 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 Rasagiline
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
Do not stop taking Rasagiline 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, this medicine can cause side effects, although not everybody gets them.

Contact you 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 (serotoninsyndrome)
- 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 in 10 people)
- Abdominal pain
- Fall
- Allergy
- Fever
- Flu (influenza)
- 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website: 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 Rasagiline

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 or blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 contains
- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as tartrate).
- The other ingredients are microcrystalline cellulose, tartric acid, maize starch, pregelatinized starch, talc, stearic acid.

What Rasagiline looks like and contents of the pack
Tablet.

Rasagiline tablets are presented as white to off-white, oblong (approximately 11.5 mm x 6 mm) bioconvex tablets, debossed with "R9SE" on one side and '1' on the other side.

The tablets are available in blister packs of 7, 10, 28, 30, 50, 90, 100 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer
Synthon Hispania S. L.
Castelló no I
Pol.Las Salinas
Sant Boi de Llobregat
Barcelona 08830
Spain

or

Synthon s.r.o.
Brněnská 32/čp. 597
Blansko 678 01
Czech Republic

or

Synthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

or

APL Swift Services (Malta) Limited
Hf26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This leaflet was last revised in 02/2021.

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