Package leaflet: Information for the user

[Invented name] 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 [invented name] is and what it is used for

[invented name] 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. [invented name] helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take [invented name]

Do not take [invented name]
- 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 [invented name]:
- 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 [invented name] treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions
Talk to your doctor or pharmacist before taking [invented name]
- 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 [invented name]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).

[invented name]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 [invented name]in children and adolescents. Therefore, [invented name] is not recommended for use under the age of 18.

Other medicines and [invented name]
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 [invented name] together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.
If you are starting treatment with [invented name], 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 [invented name] treatment.

Tell your doctor or pharmacist if you are smoking or intend to stop smoking. Smoking could decrease the amount of [invented name]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 [invented name] if you are pregnant, as the effects of [invented name] 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 [invented name] may influence your ability to do so. [invented name] 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 [invented name]. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking [invented name]do not drive or operate machinery (see section 2).

3. How to take [invented name]

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 of [invented name] is 1 tablet of 1 mg taken by mouth once daily.
[invented name] may be taken with or without food.

If you take more [invented name] than you should
If you think that you may have taken too many [invented name] tablets, contact your doctor or pharmacist immediately. Take the [invented name] carton/blister or bottle with you to show the doctor or pharmacist.

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

If you forget to take [invented name]
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 [invented name]
Do not stop taking [invented name] 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 (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).

<u>Other side effects</u>

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. 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 Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [invented name]

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

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What [invented name] contains
- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as rasagiline tartrate).
- The other ingredients are Cellulose, Microcrystalline; Maize starch; Starch, Pregalatinised (from maize); Talc; Sodium Stearyl Fumarate.

What [invented name] looks like and contents of the pack
[invented name] tablets are presented as white to off-white, round, flat, bevelled tablets (6.5 mm).

DE/H/4367/001/DC

Pack sizes of 7, 10 , 28, 30, 60, 100, 112 tablets in blisters
Pack sizes of 30 tablets in tablet containers with child-resistant screw caps containing desiccant (silica gel). The desiccant, used to keep the tablets dry, should not be swallowed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

DE/H/4367/001/DC

Germany	Rasagilin Accord 1mg Tabletten
Austria	Rasagilin Accord 1mg Tabletten
Bulgaria	Rasagiline Accord 1mg таблетки
Denmark	Rasagilin Accord
Estonia	Rasagiline Accord
Finland	Rasagiline Accord 1mg Tabletti
France	Rasagiline Accord 1mg comprimé
Ireland	Rasagiline Accord 1mg tablets
Italy	Rasagilina Accord
Lithuania	Rasagiline Accord 1mg tabletės
Latvia	Rasagiline Accord 1mg tabletes
Norway	Rasagilin Accord 1mg tabletter
Poland	Rasagiline Accord
Sweden	Rasagiline Accord 1mg tabletter
Slovak Republic	Rasagiline Accord 1mg tablety
United Kingdom	Rasagiline Accord 1mg tablets

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