

Package leaflet: Information for the user

Rasagiline Rowex 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 Rowex is and what it is used for
2. What you need to know before you take Rasagiline Rowex
3. How to take Rasagiline Rowex
4. Possible side effects
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1. What Rasagiline Rowex is and what it is used for

Rasagiline Rowex 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 Rowex helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take Rasagiline Rowex

Do not take Rasagiline Rowex

- 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 Rowex:

- 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 Rowex treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions

Talk to your doctor before taking Rasagiline Rowex

- if you have any liver problems.
- you should speak with your doctor about any suspicious skin changes. Treatment with Rasagiline Rowex may possibly increase the risk of skin cancer.
- if you are taking buprenorphine-containing medicinal products. The use of these medicines together with Rasagiline Rowex can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Rasagiline Rowex").

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 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 Rowex may cause drowsiness and may cause you to suddenly fall asleep during daytime 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 Rowex in children and adolescents. Therefore, Rasagiline Rowex is not recommended for use under the age of 18.

Other medicines and Rasagiline Rowex

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 or might take any of the following medicines:

- buprenorphine-containing medical products to treat severe pain. These medicines may interact with Rasagiline Rowex and you may experience a so called serotonin syndrome with 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.
- 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 Rowex together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.

If you are starting treatment with Rasagiline Rowex, 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 Rowex treatment.

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

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 Rowex if you are pregnant, as the effects of Rasagiline Rowex 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 Rowex may influence your ability to do so. Rasagiline Rowex 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 Rowex. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking

Rasagiline Rowex do not drive or operate machinery (see section 2).

Rasagiline Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Rasagiline Rowex

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

If you take more Rasagiline Rowex than you should

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

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

If you forget to take Rasagiline Rowex

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 Rowex

Do not stop taking Rasagiline Rowex 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 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 may be an increased risk of skin cancer (melanoma) with the use of this medicine (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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rasagiline Rowex

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, tablet container or blister. 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 Rasagiline Rowex contains

- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as rasagiline tartrate).
- The other ingredients are Cellulose Microcrystalline; Maize starch; Starch Pregelatinised (from maize); Talc; Sodium Stearyl Fumarate.

What Rasagiline Rowex looks like and contents of the pack

Rasagiline Rowex tablets are presented as white to off-white, round, flat, bevelled tablets (6.5 mm).

Pack sizes of 10, 28, 30, 98, 100, 112 tablets in blisters

Pack sizes of 30, 100 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 Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Delorbis Pharmaceuticals Ltd, 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, Lefkosia, Cyprus.
Iberfar – Indústria Farmacêutica, S.A., Rua Consiglieri Pedroso, no. 121-123, Queluz de Baixo, Barcarena, Portugal.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, Barleben, Germany.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Germany	Rasagilin – 1 A Pharma 1 mg Tabletten
Austria	Rasagilin Sandoz 1 mg Tabletten
Denmark	Rasagiline “Sandoz”
Spain	Rasagilina Sandoz Farmacéutica 1 mg comprimidos EFG
Finland	Rasagiline Sandoz 1 mg tabletti
France	RASAGILINE SANDOZ 1 mg comprimés
Hungary	Razagilin Sandoz 1 mg tableta
Ireland	Rasagiline Rowex 1 mg tablets
Lithuania	Rasagiline Sandoz 1 mg tabletės
The Netherlands	Rasagiline Sandoz 1 mg tabletten
Portugal	Rasagilina Sandoz
Sweden	Rasagiline Sandoz 1 mg tablettor
Slovenia	Razagilin Sandoz 1 mg tablete
Slovakia	Rasagiline Sandoz 1 mg tablety

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