

# 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 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
5. How to store Rasagiline Rowex
6. Contents of the pack and other information

**ROWEX<sup>®</sup>**

## 1 What Rasagiline Rowex is and what it is used for

Rasagiline Rowex 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 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 or pharmacist before taking Rasagiline Rowex

- if you have mild to moderate liver problems
- You should speak with your doctor about any suspicious skin changes.

### Children and adolescents

Rasagiline Rowex is not recommended for use in children and adolescents under the age of 18 years.

### Other medicines and Rasagiline Rowex

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

Ask your doctor for advice before taking any of the following medicines together with Rasagiline Rowex:

- 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 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.

### 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.

### Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Ask your doctor for advice prior to driving or using machines.

## 3 How to take Rasagiline Rowex

Always take this medicine exactly as your doctor 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 once daily.

Oral use.

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 with you to show the doctor or pharmacist.

### 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. The following side effects have been reported in placebo controlled clinical trials:

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

- abnormal movements (dyskinesia)
- headache

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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)

In addition, skin cancer was reported in around 1% of patients in the placebo controlled clinical trials. Nevertheless, scientific evidence suggests that Parkinson's disease, and not any medicine in particular, is associated with a higher risk of skin cancer (not exclusively melanoma). You should speak with your doctor about any suspicious skin changes.

Parkinson's disease is associated with symptoms of hallucinations and confusion.

In post marketing experience these symptoms have also been observed in Parkinson's disease patients treated with Rasagiline Rowex.

There have been cases of patients who, while taking one or more medications for the treatment of Parkinson's disease, were unable to resist the impulse, drive or temptation to perform an action that could be harmful to themselves or others. These are called impulse control disorders. In patients taking Rasagiline Rowex and/or other medications used to treat Parkinson's disease, the following have been observed:

- Obsessive thoughts or impulsive behaviour.
- Strong impulse to gamble excessively despite serious personal or family consequences.
- Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
- Uncontrollable excessive shopping or spending.

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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 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, Pregalatinised (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.

**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.

Sofarimex – Indústria Química e Farmacêutica, S.A., Av. das Indústrias – Alto do Colaride, Cacém, Portugal.

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

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

Germany	Rasagilin – 1 A Pharma 1 mg Tabletten
Austria	Rasagilin Sandoz 1 mg Tabletten
Belgium	Rasagilin Sandoz 1 mg tabletten
Bulgaria	Разагилин Сандоз 1 mg таблетки
Denmark	Rasagiline Rowex Sandoz 1 mg
Estonia	Rasagiline Sandoz
Spain	Rasagilina Sandoz Farmacéutica 1 mg comprimidos EFG
Finland	Rasagiline Sandoz 1 mg tabletti
France	RASAGILINE SANDOZ 1 mg comprimés
Croatia	Razagilin Sandoz 1 mg tablete
Hungary	Razagilin Sandoz 1 mg tableta
Ireland	Rasagiline Rowex 1 mg tablets
Lithuania	Rasagiline Sandoz 1 mg tabletės
Luxembourg	Rasagilin Sandoz 1 mg comprimés
Latvia	Rasagiline Sandoz 1 mg tabletes
The Netherlands	Rasagiline Sandoz 1 mg tabletten
Poland	Rasagiline Sandoz 1 mg
Portugal	Rasagilina Sandoz
Romania	Rasagilină Sandoz 1 mg comprimate
Sweden	Rasagiline Sandoz 1 mg tabletter
Slovenia	Razagilin Sandoz 1 mg tablete
Slovak Republic	Rasagiline Sandoz 1 mg tablety

**This leaflet was last revised in 10/2015.**

I.M. L/927a 11-15

Isabel Felício  
Approved by Iberfar  
(codes and dimensions)  
IBERFAR, Indústria  
Farmacêutica, S.A. -  
Serviço de Controlo da  
Qualidade -  
[ifelicio@iberfar.pt](mailto:ifelicio@iberfar.pt)  
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