

Package leaflet: Information for the user

Rasagiline Accord 1mg tablets

Rasagiline

Read all of this leaflet carefully before you start taking this medicine cause 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 Accord is and what it is used for
2. What you need to know before you take Rasagiline Accord
3. How to take Rasagiline Accord
4. Possible side effects
5. How to store Rasagiline Accord
6. Contents of the pack and other information

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

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

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

Do not take Rasagiline Accord

- 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 Accord :

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Rasagiline Accord

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

Children and adolescents

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

Other medicines and Rasagiline Accord

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 Accord :

- 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 Accord together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.

If you are starting treatment with Rasagiline Accord , 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 Accord 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 Accord

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 Accord is 1 tablet of 1 mg once daily.

Oral use.

Rasagiline Accord may be taken with or without food.

If you take more Rasagiline Accord than you should

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

If you forget to take Rasagiline Accord

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 Accord

Do not stop taking Rasagiline Accord 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

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 Accord .

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 Accord 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 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 (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance Earlsfort Terrace,

IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie

5. How to store Rasagiline Accord

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 Accord 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 Accord looks like and contents of the pack

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

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

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Accord Healthcare Limited
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North Harrow, Middlesex, HA1 4HF,
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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

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

Name of the Member State	Name of the medicinal product
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 tablett
Poland	Poland Rasagiline Accord
Sweden	Rasagiline Accord 1mg tablett
Slovak Republic	Rasagiline Accord 1mg tablety
United Kingdom	Rasagiline Accord 1mg tablets

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