

Package leaflet: Information for the user

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

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

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

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

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 or pharmacist before taking Rasagiline

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

Children and adolescents

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

Other medicines and Rasagiline

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:

- 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 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 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 Torrent

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 is 1 tablet of 1 mg once daily.

Oral use.

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 with you to show the doctor or pharmacist.

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. 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.

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 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 Yellow Card Scheme; Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rasagiline Torrent

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. 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 Torrent 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 Torrent looks like and contents of the pack

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

Pack sizes of 7, 10, 14, 20, 28, 30, 40, 42, 50, 56, 60, 70, 80, 84, 90, 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 Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in 10/2015

01042876-V0

 **Colour Black**

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:		
SIZE : 200 x 300 mm_Front/Back Side	CODE :-	DATE : 21-11-2015		
REMARK : Folding Length 38 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			
This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.				



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