

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rasagiline Teva 1 mg Tablets rasagiline

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What Rasagiline Teva is and what it is used for
2. Before you take Rasagiline Teva
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1. WHAT RASAGILINE TEVA IS AND WHAT IT IS USED FOR

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

2. BEFORE YOU TAKE RASAGILINE TEVA

Do not take Rasagiline Teva

- if you are allergic (hypersensitive) to rasagiline or any of the other ingredients of Rasagiline Teva.
- if you have severe liver problems.

Do not take the following medicines while taking Rasagiline Teva:

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

Take special care with Rasagiline Teva

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

Children

Rasagiline Teva is not recommended for use under the age of 18.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription 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 Teva:

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

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

Taking Rasagiline Teva with food and drink

Rasagiline Teva may be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 TEVA

Always take Rasagiline Teva exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Rasagiline Teva is 1 tablet of 1 mg taken by mouth once daily. Rasagiline Teva may be taken with or without food.

If you take more Rasagiline Teva than you should

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

If you forget to take Rasagiline Teva

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 Teva

Do not stop taking Rasagiline Teva without first talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rasagiline Teva 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 Teva.

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 Teva 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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RASAGILINE TEVA

Keep out of the sight and reach of children.

Do not use Rasagiline Teva 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.

Do not store above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rasagiline Teva contains

- The active substance is rasagiline (as mesilate). Each tablet contains rasagiline mesilate equivalent to 1 mg rasagiline.
- The other ingredients are mannitol, colloidal anhydrous silica, maize starch, pregelatinised maize starch, stearic acid, talc.

What Rasagiline Teva looks like and contents of the pack

Rasagiline Teva tablets are presented as white to off-white, round, flat, bevelled tablets of 8 mm diameter, debossed with "GIL" and "1" underneath on one side and plain on the other side.

The tablets are available in blister packs of 7, 10, 28, 30, 100 and 112 tablets, in perforated unit dose blister packs of 10 x 1, 30 x 1 and 100 x 1 tablets or in a bottle containing 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva B.V.
Swensweg 5,
2031 GA Haarlem,
The Netherlands

Manufacturer

Teva Pharmaceuticals Europe B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

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

Belgium	Rasagiline Teva 1 mg Tabletten/Comprimés
Germany	Rasagilin AbZ 1 mg Tabletten
Denmark	Rasagiline Teva
Estonia	Rasagiline Teva
Spain	Rasagilina Teva 1 mg comprimidos EFG
France	Rasagiline Teva 1 mg, comprimé
Croatia	Razagilin Teva1 mg tablete
Ireland	Rasagiline Teva 1 mg Tablets
Italy	Rasagilina Teva
Latvia	Rasagiline Teva 1 mg tabletes
Malta	Rasagiline Teva 1 mg Tablets
Portugal	Rasagilina Teva 1 mg comprimidos
Slovenia	Razagilin Teva 1 mg tablete
Slovakia	Razagilin Teva 1 mg tablety
United Kingdom	Rasagiline Teva 1 mg tablets

This leaflet was last revised in March 2017.