Package leaflet: Information for the patient

Rasagiline Krka 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 Krka is and what it is used for

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

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

Do not take Rasagiline Krka:
- 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 Krka:
- 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 Krka treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions
Talk to your doctor before taking Rasagiline Krka
- if you any liver problems
- you should speak with your doctor about any suspicious skin changes.

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 Krka and/or other medicines 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 Krka may cause drowsiness and may cause you to suddenly fall asleep during day time 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 Krka in children and adolescents. Therefore, Rasagiline Krka is not recommended for use under the age of 18.

Other medicines and Rasagiline Krka
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 any of the following medicines:
- 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 Krka together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.
If you are starting treatment with Rasagiline Krka, 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 Krka treatment.

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

Rasagiline Krka with food and drink and alcohol

Rasagiline Krka may be taken with or without food.

Pregnancy, breast-feeding and fertility
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 Krka if you are pregnant, as the effects of Rasagiline Krka 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 Krka may influence your ability to do so. Rasagiline Krka 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 Krka. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking Rasagiline Krka do not drive or operate machinery (see section 2).

3. How to take Rasagiline Krka

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

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

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

If you forget to take Rasagiline Krka
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 Krka
Do not stop taking Rasagiline Krka 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 you 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 is a higher risk of skin cancer (not exclusively melanoma) in patients with parkinson's disease (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:
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 Krka

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 blister and box after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original blister in order to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What Rasagiline Krka contains

- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as rasagiline hemitartrate).
- The other ingredients (excipients) are microcrystalline cellulose (E460), pregelatinised maize starch (type 1500), colloidal anhydrous silica (E551), talc (E553b) and stearic acid.

What Rasagiline Krka looks like and contents of the pack

Tablets are white to almost white, round, slightly biconvex, 7 mm in diameter, with beveled edges, darker spots may be visible.

Rasagiline Krka is available in boxes containing:

- 14, 15, 28, 30 and 112 tablets in blisters,
- 14 x 1, 15 x 1, 28 x 1, 30 x 1 and 112 x 1 tablets in perforated unit dose blisters,
- 14 x 1, 15 x 1, 28 x 1, 30 x 1 and 112 x 1 tablets in perforated unit dose blisters with the names of days (calendar packs).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Krka, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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
Austria	Rasagalin HCS
Denmark, Finland, Iceland, Sweden, Norway	Rasagilin Krka
Cyprus, Netherlands, Belgium, Ireland, France	Rasagiline Krka
Spain, Italy	Rasagilina Krka
United Kingdom	Rasagiline
Slovenia	Razagilin Krka

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