Package leaflet: Information for the user

Rasagiline Actavis 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 Actavis is and what it is used for

Rasagiline Actavis contains the active substance rasagaline 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 Actavis helps to increase and sustain levels of dopamine in the brain.

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

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Rasagiline Actavis
- If you have mild to moderate 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 Actavis 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. (See section 4)

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

Other medicines and Rasagiline Actavis
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 Actavis:
- 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 Actavis together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.
If you are starting treatment with Rasagiline Actavis, 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 Actavis treatment.

Pregnancy,breast-feeding and fertility
Rasagiline Actavis may affect the ability to breast-feed your baby.
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 Actavis if you are pregnant, as the effects of Rasagiline Actavis 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 Actavis may influence your ability to drive and operate machines. Rasagiline Actavis may 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 take Rasagaline Actavis. If you are experiencing somnolence or new episodes of falling asleep without warning during daily activities, do not drive or operate machinery (see section 2). Ask your doctor for advice prior to driving or using machines.

3. How to take Rasagiline Actavis

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist or if you are not sure.

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

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

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

If you forget to take Rasagiline Actavis
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 Actavis
Do not stop taking Rasagiline Actavis 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.

Seek medical help straight 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).

<u>Other side effects</u>

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 Actavis

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

Store in the original package in order to protect from light.

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 Actavis contains

- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as tartrate).
- The other ingredients are Calcium sulfate dehydrate, Starch, pregelatinised (maize), Maize starch, Stearic acid 50, Talc, Citric acid anhydrous, Silica colloidal anhydrous.

What Rasagiline Actavis looks like and contents of the pack

White, round bevel edge, 7 mm, debossed with "A486" on one side and plain on the other side.

The tablets are available in blister packs of 10, 28, 30 56, 60 or 100 tablets or in a bottle containing 30, 100 or 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Actavis Group PTC ehf,
Reykjavikurvegi 76-78,
220 Hafnarfjordur,
Iceland

Manufacturer
Actavis Group PTC ehf,
Reykjavikurvegi 76-78,
220 Hafnarfjordur,
Iceland

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

AT	Rasagilin Actavis 1 mg Tabletten
DK	Rasagilin Actavis
EE	Rasagiline Actavis
EL	Rasagiline Actavis
FI	Rasagilin Actavis
HU	Rasagiline Actavis 1 mg tabletta
IE	Rasagiline Actavis 1 mg Tablets
IS	Rasagilin Actavis
LT	Rasagiline Actavis 1 mg tabletės
MT	Rasagiline Actavis
NO	Rasagilin Actavis
PL	Rasagiline Actavis
RO	Rasagilină Actavis 1 mg comprimate
SE	Rasagilin Actavis
SK	Rasagiline Actavis 1 mg
UK	Rasagiline Actavis 1 mg Tablets

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