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EPAR summary for the public

Rasagiline ratiopharm

rasagiline

This is a summary of the European public assessment report (EPAR) for Rasagiline ratiopharm. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Rasagiline ratiopharm.

For practical information about using Rasagiline ratiopharm, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rasagiline ratiopharm and what is it used for?

Rasagiline ratiopharm is a medicine used to treat adults with Parkinson's disease (a progressive brain disorder that causes shaking, slow movement and muscle stiffness).

Rasagiline ratiopharm can be used either alone, or as an add-on to levodopa (another medicine used in Parkinson's disease) in patients who are having 'fluctuations' towards the end of the period between levodopa doses. Fluctuations happen when the effects of the medication wear off and symptoms re-emerge. They are linked to a reduction in the effect of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and having difficulty moving about.

This medicine is the same as Azilect, which is already authorised in the European Union (EU). The company that makes Azilect has agreed that its scientific data can be used for Rasagiline ratiopharm ('informed consent').

Rasagiline ratiopharm contains the active substance rasagiline.

How is Rasagiline ratiopharm used?

Rasagiline ratiopharm is available as tablets (1 mg). The standard dose is one tablet once a day.

The medicine can only be obtained with a prescription.

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How does Rasagiline ratiopharm work?

The active substance in Rasagiline ratiopharm, rasagiline, is a 'monoamine oxidase B inhibitor'. It blocks the enzyme monoamine oxidase type B, which breaks down the neurotransmitter dopamine in the brain. Neurotransmitters are chemicals that allow nerve cells to communicate with one another. In patients with Parkinson's disease, the cells that produce dopamine die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. By increasing levels of dopamine in the parts of the brain that control movement and coordination, Rasagiline ratiopharm improves the signs and symptoms of Parkinson's disease, such as stiffness and slowness of movement.

What benefits of Rasagiline ratiopharm have been shown in studies?

Rasagiline ratiopharm has been shown in three studies, involving 1,563 patients, to be effective in both relieving the symptoms of Parkinson's disease and in reducing the time patients spend in their 'off' periods. In one of the studies, a 26-week treatment with Rasagiline ratiopharm resulted in an average fall of 0.13 points in UPDRS (a standard scale for assessing symptoms of Parkinson's disease) from a starting value of 24.69 compared with a rise of 4.07 points in the patients taking placebo from a starting value of 24.54. A fall in the UPDRS score indicates an improvement in symptoms, while a rise indicates a worsening of symptoms.

In the two other studies, Rasagiline ratiopharm was given as 'add-on' to patients with later stage disease who were already being treated with levodopa, and compared with placebo and another medicine entacapone (also used as add-ons). The studies included 1,159 patients and lasted 26 and 18 weeks, respectively. In both studies, patients taking Rasagiline ratiopharm spent an average of around one hour less in the 'off' state than those taking placebo. Similar reductions in time spent in the 'off' state were seen in patients taking entacapone.

What are the risks associated with Rasagiline ratiopharm?

The most common side effect with Rasagiline ratiopharm (seen in more than 1 patient in 10) is headache. For the full list of all side effects reported with Rasagiline ratiopharm, see the package leaflet.

Rasagiline ratiopharm must not be used with other monoamine oxidase inhibitors including medicines and herbal preparations without prescription such as St John's wort (used to treat depression). It must also not be used with pethidine (a painkiller). There should be at least 14 days between stopping treatment with Rasagiline ratiopharm and starting treatment with another monoamine-oxidase inhibitor or with pethidine. Rasagiline ratiopharm must not be used in patients who have severe problems with their liver. It is not recommended for patients with moderate liver problems. Patients with mild liver problems should use Rasagiline ratiopharm with caution and should stop treatment if their liver problems get worse.

For the full list of all side effects and restrictions with Rasagiline ratiopharm, see the package leaflet.

Why is Rasagiline ratiopharm approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Rasagiline ratiopharm's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Rasagiline ratiopharm?

A risk management plan has been developed to ensure that Rasagiline ratiopharm is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rasagiline ratiopharm, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Rasagiline ratiopharm

The European Commission granted a marketing authorisation valid throughout the European Union for Rasagiline ratiopharm on 12 January 2015.

The full EPAR and risk management plan summary for Rasagiline ratiopharm can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Rasagiline ratiopharm, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.