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EPAR summary for the public

Rasagiline Mylan

rasagiline

This is a summary of the European public assessment report (EPAR) for Rasagiline Mylan. 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 Mylan.

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

What is Rasagiline Mylan and what is it used for?

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

Rasagiline Mylan 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 in the control of their condition. Fluctuations happen when the effects of the medication wear off and symptoms re-emerge before the next dose is due. 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.

Rasagiline Mylan is a 'generic medicine'. This means that Rasagiline Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Azilect. For more information on generic medicines, see the question-and-answer document here.

Rasagiline Mylan contains the active substance rasagiline.

How is Rasagiline Mylan used?

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

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The medicine can only be obtained with a prescription.

How does Rasagiline Mylan work?

The active substance in Rasagiline Mylan, rasagiline, is a 'monoamine oxidase B inhibitor'. It blocks the enzyme monoamine oxidase type B, which breaks down a substance called dopamine in the brain. Dopamine is important for controlling movement and coordination. In patients with Parkinson's disease, the cells that produce dopamine begin to 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 Mylan reduces the symptoms of Parkinson's disease, such as stiffness and slowness of movement.

How has Rasagiline Mylan been studied?

Because Rasagiline Mylan is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Azilect. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Rasagiline Mylan?

Because Rasagiline Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Rasagiline Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Rasagiline Mylan has been shown to have comparable quality and to be bioequivalent to Azilect. Therefore, the CHMP's view was that, as for Azilect, the benefit outweighs the identified risk. The Committee recommended that Rasagiline Mylan be approved for use in the EU.

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

A risk management plan has been developed to ensure that Rasagiline Mylan 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 Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Rasagiline Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Rasagiline Mylan on 4 April 2016.

The full EPAR for Rasagiline Mylan 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 Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 04-2016.