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Rasagiline Viatris[1] (*rasagiline*)

An overview of Rasagiline Viatris and why it is authorised in the EU

What is Rasagiline Viatris and what is it used for?

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

Rasagiline Viatris 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 Viatris contains the active substance rasagiline and is a 'generic medicine'. This means that Rasagiline Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Rasagiline Viatris is Azilect. For more information on generic medicines, see the question-and-answer document here.

How is Rasagiline Viatris used?

Rasagiline Viatris is available as tablets. The standard dose is one tablet once a day.

The medicine can only be obtained with a prescription.

For more information about using Rasagiline Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Rasagiline Viatris work?

The active substance in Rasagiline Viatris, 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

[1] Previously known as Rasagiline Mylan.

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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 Viatris reduces the symptoms of Parkinson's disease, such as stiffness and slowness of movement.

How has Rasagiline Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Azilect, and do not need to be repeated for Rasagiline Viatris.

As for every medicine, the company provided studies on the quality of Rasagiline Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Rasagiline Viatris?

Because Rasagiline Viatris 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 Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Rasagiline Viatris has been shown to have comparable quality and to be bioequivalent to Azilect. Therefore, the Agency's view was that, as for Azilect, the benefit outweighs the identified risk and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rasagiline Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Azilect also apply to Rasagiline Viatris where appropriate.

As for all medicines, data on the use of Rasagiline Viatris are continuously monitored. Suspected side effects reported with Rasagiline Viatris are carefully evaluated and any necessary action taken to protect patients.

Other information about Rasagiline Viatris

Rasagiline Mylan received a marketing authorisation valid throughout the EU on 4 April 2016.

The name of the medicine was changed to Rasagiline Viatris on 29 July 2024.

Further information on Rasagiline Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rasagiline-viatris. Information on the reference medicine can also be found on the Agency's website.

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