LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Rasagiline Teva
(rasagiline mesilate)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Rasagiline Teva
(rasagiline mesilate)

Tablet, 1 mg

This is a summary of the public assessment report (PAR) for Rasagiline Teva. It explains how Rasagiline Teva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Rasagiline Teva.

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

What is Rasagiline Teva and what is it used for?

Rasagiline Teva is a 'generic medicine'. This means that Rasagiline Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Azilect.

Rasagiline Teva is used for the treatment of Parkinson's disease. It can be used together with or without Levodopa (another medicine that is used to treat Parkinson's disease).

How does Rasagiline Teva work?

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

How is Rasagiline Teva used?

The pharmaceutical form of Rasagiline Teva is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Rasagiline Teva have been shown in studies?

No additional studies were needed as Rasagiline Teva is a generic medicine that is identical to the reference medicine, Azilect.

What are the possible side effects of Rasagiline Teva?

Because Rasagiline Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Rasagiline Teva approved?

It was concluded that, in accordance with EU requirements, Rasagiline Teva has been shown to have comparable quality and to be bioequivalent to the reference medicine Azilect. Therefore, the Medical Products Agency in Sweden decided that, as for Azilect, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Rasagiline Teva

The marketing authorisation for Rasagiline Teva was granted on 2015-12-04 in Sweden.

The full PAR for Rasagiline Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Rasagiline Teva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2015-12-04.