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EPAR summary for the public

Azilect

rasagiline

This is a summary of the European public assessment report (EPAR) for Azilect. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Azilect.

What is Azilect?

Azilect is a medicine that contains the active substance rasagiline. It is available as tablets (1 mg).

What is Azilect used for?

Azilect is used to treat Parkinson's disease. Parkinson's disease is a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Azilect 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 are linked to a reduction in the effects of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and immobile.

Azilect can only be obtained with a prescription.

How is Azilect used?

The standard dose of Azilect is one tablet once a day.

How does Azilect work?

The active substance in Azilect, rasagiline, is a 'monoamine oxidase-B inhibitor'. It blocks the enzyme monoamine oxidase type B, which breaks down the neurotransmitter dopamine in the brain.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Neurotransmitters are chemicals that nerve cells use to communicate with neighbouring cells. 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 co-ordination, Azilect improves the signs and symptoms of Parkinson's disease, such as stiffness and slowness of movement.

How has Azilect been studied?

Azilect has been studied in three main studies involving a total of 1,563 patients with Parkinson's disease. In the first study, two different doses of Azilect taken alone were compared with placebo (a dummy treatment) in 404 patients with early-stage disease. The main measure of effectiveness was the change in symptoms over 26 weeks, as assessed on a standard scale (Unified Parkinson's Disease Rating Scale, UPDRS).

The other two studies involved a total of 1,159 patients with later stage disease, where Azilect was added to the patients' existing treatment including levodopa. It was compared with placebo or entacapone (another medicine for Parkinson's disease). The studies lasted 26 and 18 weeks, respectively. The main measure of effectiveness was the time spent in the 'off' state during the day, as recorded in patients' diaries.

What benefit has Azilect shown during the studies?

Azilect was more effective than placebo in all of the studies. In the study where Azilect was used alone, patients taking 1 mg of the medicine once a day had an average fall in UPDRS score of 0.13 points over the 26-week study from a starting value of 24.69. This was 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.

When used as an add-on to levodopa, 1 mg Azilect reduced the time in the 'off' state more than placebo did. In both studies, patients adding Azilect spent an average of around one hour less in the 'off' state than those adding placebo. A similar decrease in time spent in the 'off' state was seen in patients taking entacapone.

What is the risk associated with Azilect?

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

Azilect must not be used with other monoamine oxidase inhibitors including medicines and herbal preparations obtained without prescription such as St John's wort. It must also not be used with pethidine (a painkiller). There should be at least 14 days between stopping treatment with Azilect and starting treatment with another monoamine oxidase inhibitor or with pethidine. Azilect must not be used in patients who have severe problems with their liver. For the full list of restrictions, see the package leaflet.

Why has Azilect been approved?

The CHMP decided that Azilect's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Azilect

The European Commission granted a marketing authorisation valid throughout the European Union for Azilect on 21 February 2005.

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

This summary was last updated in 04-2016.