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EPAR summary for the public

Rivastigmine Actavis

rivastigmine

This is a summary of the European public assessment report (EPAR) for Rivastigmine Actavis. 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 Rivastigmine Actavis.

What is Rivastigmine Actavis?

Rivastigmine Actavis is a medicine containing the active substance rivastigmine. It is available as capsules (1.5, 3, 4.5 and 6 mg).

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

What is Rivastigmine Actavis used for?

Rivastigmine Actavis is used for the treatment of patients with mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.

It can also be used to treat mild to moderately severe dementia in patients with Parkinson's disease.

The medicine can only be obtained with a prescription.

How is Rivastigmine Actavis used?

Treatment with Rivastigmine Actavis should be initiated and supervised by a doctor who has experience in the diagnosis and treatment of Alzheimer's disease or dementia in patients with Parkinson's disease. Treatment should only be started if a caregiver is available who will regularly monitor the use of Rivastigmine Actavis by the patient. Treatment should continue as long as the medicine has a benefit, but the dose can be reduced or treatment interrupted if the patient has side effects.

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Rivastigmine Actavis should be given twice a day, with morning and evening meals. The starting dose is 1.5 mg twice a day. In patients who tolerate this dose, it can be increased in 1.5 mg steps no more frequently than every two weeks, to a regular dose of 3 to 6 mg twice a day. The highest tolerated dose should be used to get the maximum benefit, but the dose should not exceed 6 mg twice a day.

How does Rivastigmine Actavis work?

The active substance in Rivastigmine Actavis, rivastigmine, is a dementia medicine. In patients with Alzheimer's dementia or dementia due to Parkinson's disease, certain nerve cells die in the brain, resulting in low levels of the neurotransmitter acetylcholine (a chemical that allows nerve cells to communicate with each other). Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Rivastigmine Actavis allows levels of acetylcholine to increase in the brain, helping to reduce the symptoms of Alzheimer's dementia and dementia due to Parkinson's disease.

How has Rivastigmine Actavis been studied?

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

What are the benefits and risks of Rivastigmine Actavis?

Because Rivastigmine Actavis 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 has Rivastigmine Actavis been approved?

The CHMP concluded that, in accordance with EU requirements, Rivastigmine Actavis has been shown to have comparable quality and to be bioequivalent to Exelon. Therefore, the CHMP's view was that, as for Exelon, the benefit outweighs the identified risk. The Committee recommended that Rivastigmine Actavis be given marketing authorisation.

Other information about Rivastigmine Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Rivastigmine Actavis on 16 June 2011.

The full EPAR for Rivastigmine Actavis 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 Rivastigmine Actavis, 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 06-2015.