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EPAR summary for the public

Nemdatine

memantine

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

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

What is Nemdatine and what is it used for?

Nemdatine is a medicine used to treat patients with moderate to severe Alzheimer's disease, a type of dementia (a brain disorder) that gradually affects memory, intellectual ability and behaviour. It contains the active substance memantine.

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

How is Nemdatine used?

Nemdatine is available as 5 mg, 10 mg, 15 mg and 20 mg tablets and can only be obtained with a prescription.

Treatment should be started and supervised by a doctor who has experience in the diagnosis and treatment of Alzheimer's disease. Treatment should only be started if a caregiver is available who will regularly monitor the use of Nemdatine by the patient.

Nemdatine should be given once a day at the same time every day. To prevent side effects, the dose of Nemdatine is gradually increased over the first three weeks of treatment: during the first week, the dose is 5 mg; in the second week, it is 10 mg; and during the third week, it is 15 mg. From week four onwards, the recommended maintenance dose is 20 mg once a day. The tolerance and dose should be

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assessed within 3 months after starting treatment, and from then on the benefits of continuing treatment with Nemdatine should be reassessed on a regular basis. The dose may need to be reduced in patients who have moderate or severe problems with their kidneys.

For more information, see the package leaflet.

How does Nemdatine work?

The active substance in Nemdatine, memantine, is an antidementia medicine. The cause of Alzheimer's disease is unknown, but memory loss in the disease is believed to be due to a disturbance of message signals in the brain.

Memantine works by blocking special types of receptor called NMDA receptors to which the neurotransmitter glutamate normally attaches. Neurotransmitters are chemicals in the nervous system that allow nerve cells to communicate with one another. Changes in the way glutamate transmits signals within the brain have been linked to the memory loss seen in Alzheimer's disease. In addition, overstimulation of the NMDA receptors may result in cell damage or death. By blocking NMDA receptors, memantine improves the transmission of signals in the brain and reduces the symptoms of Alzheimer's disease.

How has Nemdatine been studied?

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

What are the benefits and risks of Nemdatine?

Because Nemdatine 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 Nemdatine approved?

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

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

Safety information has been included in the summary of product characteristics and the package leaflet for Nemdatine, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Nemdatine

The European Commission granted a marketing authorisation valid throughout the European Union for Nemdatine on 22 April 2013.

The full EPAR for Nemdatine 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 Nemdatine, 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 04-2013.