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EPAR summary for the public

Memantine Accord

memantine

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

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

What is Memantine Accord and what is it used for?

Memantine Accord is a medicine that contains the active substance memantine. It is 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.

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

How is Memantine Accord used?

Memantine Accord is available as tablets (5 mg, 10 mg, 15 mg and 20 mg) 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 Memantine Accord by the patient.

Memantine Accord should be given once a day at the same time every day. To prevent side effects, the dose of Memantine Accord is gradually increased over the first three weeks of treatment: during the first week, the daily 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

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

How does Memantine Accord work?

The active substance in Memantine Accord, 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 types of receptors called *N*-methyl-D-aspartate (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. By blocking NMDA receptors, memantine improves the transmission of signals in the brain and reduces the symptoms of Alzheimer's disease.

How has Memantine Accord been studied?

The company provided data on the medicine's solubility, composition and absorption in the body. No additional studies in patients were required as Memantine Accord was shown to have comparable quality and is considered to be bioequivalent to the reference medicine, Axura. 'Bioequivalent' means that the medicines are expected to produce the same levels of the active substance in the body.

What are the benefits and risks of Memantine Accord?

Because Memantine Accord 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 Memantine Accord approved?

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

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

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

Other information about Memantine Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Memantine Accord on 04 December 2013.

The full EPAR for Memantine Accord 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 Memantine Accord, 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 12-2013.