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EPAR summary for the public

Memantine LEK

memantine

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

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

What is Memantine LEK and what is it used for?

Memantine LEK 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.

Memantine LEK is a 'generic medicine'. This means that Memantine LEK 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 Memantine LEK used?

Memantine LEK is available as 10 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 Memantine LEK by the patient.

Memantine LEK should be given once a day at the same time every day. To prevent side effects, the dose of Memantine LEK 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 assessed within 3 months after starting treatment, and from then on the benefits of

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continuing treatment with Memantine LEK 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 Memantine LEK work?

The active substance in Memantine LEK, 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 Memantine LEK been studied?

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

What are the benefits and risks of Memantine LEK?

Because Memantine LEK 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 LEK approved?

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

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

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

Other information about Memantine LEK

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

The full EPAR for Memantine LEK 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 LEK, 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.