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EPAR summary for the public

Marixino[1]

memantine

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

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

What is Marixino and what is it used for?

Marixino 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 hydrochloride.

Marixino is a 'generic medicine'. This means that Marixino 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 Marixino used?

Marixino 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 Marixino by the patient.

Marixino should be given once a day at the same time every day. To prevent side effects, the dose of Marixino 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 continuing

[1] Previously known as Maruxa.

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treatment with Marixino 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 Marixino work?

The active substance in Marixino, 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 Marixino 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 Marixino was shown to have comparable quality and is considered to be bioequivalent to the reference medicine, Ebixa. '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 Marixino?

Because Marixino 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 Marixino approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Marixino 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 Marixino be approved for use in the EU.

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

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

Other information about Marixino

The European Commission granted a marketing authorisation valid throughout the European Union for Maruxa on 29 April 2013. The name of the medicine was changed to Marixino on 9 August 2013.

The full EPAR for Marixino 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 Marixino, 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 08-2013.