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EPAR summary for the public

Axura

memantine hydrochloride

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

What is Axura?

Axura is a medicine that contains the active substance memantine hydrochloride. It is available as tablets (5 mg, 10 mg, 15 mg and 20 mg). Axura is also available as an oral solution, which is supplied with a pump that delivers 5 mg memantine hydrochloride with each activation.

What is Axura used for?

Axura is used to treat patients with moderate to severe Alzheimer's disease. Alzheimer's disease is a type of dementia (a brain disorder) that gradually affects memory, intellectual ability and behaviour.

The medicine can only be obtained with a prescription.

How is Axura used?

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 Axura by the patient.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

treatment with Axura 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. If the solution is used, the dose should first be pumped onto a spoon or into a glass of water. It should not be poured or pumped directly into the mouth. For more information, see the package leaflet.

How does Axura work?

The active substance in Axura, memantine hydrochloride, 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 can 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 Axura been studied?

Axura has been studied in three main studies including a total of 1,125 patients with Alzheimer's disease, some of whom had taken other medicines for their disease in the past.

The first study involved 252 patients with moderately severe to severe disease, while the other two involved a total of 873 patients with mild to moderate disease. Axura was compared with placebo (a dummy treatment) over 24 to 28 weeks. The main measures of effectiveness were the change in symptoms in three main areas: functional (the degree of disability), cognitive (the ability to think, learn and remember) and global (a combination of several areas including general function, cognitive symptoms, behaviour and the ability to carry out everyday activities).

Axura was also studied in three additional studies including a total of 1,186 patients with mild to severe disease.

What benefit has Axura shown during the studies?

Axura was more effective than placebo at controlling the symptoms of Alzheimer's disease. In the study of moderately severe to severe disease, patients taking Axura had fewer symptoms than those taking placebo after 28 weeks, as measured on both global and functional scores. In the two studies of mild to moderate disease, patients on Axura had less severe symptoms after 24 weeks, as measured on the global and cognitive scores. However, when these results were considered along with those of the three additional studies, it was noted that the effect of Axura was smaller in patients with mild disease.

What is the risk associated with Axura?

The most common side effects with Axura (seen in between 1 and 10 patients in 100) are somnolence (sleepiness), dizziness, hypertension (high blood pressure), dyspnoea (difficulty breathing), constipation, headache and drug hypersensitivity (allergy to the medicine). For the full list of all side effects reported with Axura, see the package leaflet.

Axura must not be used in people who are hypersensitive (allergic) to memantine hydrochloride or any of the other ingredients.

Why has Axura been approved?

The CHMP decided that Axura's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Axura

The European Commission granted a marketing authorisation valid throughout the European Union for Axura on 17 May 2002.

The full EPAR for Axura 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 Axura, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2011.