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Questions and answers

Withdrawal of the marketing authorisation application for Memantine FGK (memantine)

On 10 January 2013, FGK Representative Service GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Memantine FGK, for the treatment of patients with moderate to severe Alzheimer's disease.

What is Memantine FGK?

Memantine FGK is a medicine that contains the active substance memantine. It was to be available as prolonged-release capsules (7, 14, 21, and 28 mg). Prolonged-release capsules release the active substance slowly over a few hours.

Memantine FGK was developed as a 'hybrid medicine'. This means that it is similar to a reference medicine, Axura, containing the same active substance, but Memantine FGK is available at different strengths and as prolonged-release capsules designed to release the active substance more gradually than Axura tablets.

What was Memantine FGK expected to be used for?

Memantine FGK was expected to be used for the treatment of 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.

How is Memantine FGK expected to work?

Memantine FGK is expected to work in the same way as the reference medicine, Axura. The active substance in Memantine FGK and Axura, 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

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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.

What did the company present to support its application?

The company presented the results of studies carried out to investigate the levels of the active substance achieved in the body after Memantine FGK was taken. The company also presented one main study of the effectiveness of Memantine FGK involving around 660 patients with moderate to severe Alzheimer's disease. The medicine was compared with placebo (a dummy treatment) and the main measures of effectiveness were the change in symptoms in two areas, cognitive (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). Patients also received cholinesterase inhibitors, another kind of medicine for Alzheimer's disease.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal the CHMP had some concerns and was of the provisional opinion that Memantine FGK could not have been approved for the treatment of moderate to severe Alzheimer's disease. In particular, the fact that the medicine was compared with placebo, rather than the reference product, made it difficult to properly compare the safety and effectiveness of the prolonged-release formulation with the reference medicine. The Committee considered that the choice of dose for Memantine FGK had not been properly justified.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the company had not provided enough data to support the application for Memantine FGK.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it decided to withdraw the application for strategic reasons.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no ongoing clinical trials or compassionate use programmes with Memantine FGK.