European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NIMVASTID

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Nimvastid?

Nimvastid is a medicine that contains the active substance rivastigmine. It is available as capsules (yellow: 1.5 mg, orange: 3 mg, brownish red: 4.5 mg, and brownish red and orange: 6 mg) and as white orodispersible tablets (1.5 mg, 3 mg, 4.5 mg, and 6 mg). Orodispersible means that the tablets dissolve in the mouth.
Nimvastid is a 'generic medicine'. This means that Nimvastid is similar to a 'reference medicine' already authorised in the European Union (EU) called Exelon. For more information on generic medicines, see the question-and-answer document here.

What is Nimvastid used for?

Nimvastid is used for the treatment of patients with mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.
It is also used to treat mild to moderately severe dementia in patients with Parkinson's disease.
The medicine can only be obtained with a prescription.

How is Nimvastid used?

Treatment with Nimvastid should be initiated and supervised by a doctor who has experience in the diagnosis and treatment of Alzheimer's disease or dementia in patients with Parkinson's disease. Treatment should only be started if a caregiver is available who will regularly monitor the use of Nimvastid by the patient. Treatment should continue as long as the medicine has a benefit, but the dose can be reduced or treatment interrupted if the patient has side effects.
Nimvastid should be given twice a day, with morning and evening meals. The capsules should be swallowed whole. Nimvastid orodispersible tablets should be placed on the tongue, where they disintegrate quickly in the saliva before being swallowed.
The starting dose for Nimvastid is 1.5 mg twice a day. In patients who tolerate this dose, it can be increased in 1.5-mg steps no more frequently than every two weeks, to a regular dose of 3 to 6 mg twice a day. The highest tolerated dose should be used to get the maximum benefit, but the dose should not exceed 6 mg twice a day.

How does Nimvastid work?

The active substance in Nimvastid, rivastigmine, is an antidementia medicine. In patients with Alzheimer's dementia or dementia due to Parkinson's disease, certain nerve cells die in the brain,

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resulting in low levels of the neurotransmitter acetylcholine (a chemical that allows nerve cells to communicate with each other). Rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Nimvastid allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's dementia and dementia due to Parkinson's disease.

How has Nimvastid been studied?
Because Nimvastid is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine (this means that the two medicines produce the same levels of the active substance in the body).

What are the benefit and risk of Nimvastid?
Because Nimvastid is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Nimvastid been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Nimvastid has been shown to have comparable quality and to be bioequivalent to Exelon. Therefore, the CHMP's view was that, as for Exelon, the benefit outweighs the identified risk. The Committee recommended that Nimvastid be given marketing authorisation.

Other information about Nimvastid:
The European Commission granted a marketing authorisation valid throughout the European Union for Nimvastid to KRKA,d.d., Novo mesto on 11 May 2009.

The full EPAR for Nimvastid can be found here.

This summary was last updated in 05-2009.