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EPAR summary for the public

Rivastigmine Hexal

rivastigmine

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

What is Rivastigmine Hexal?

Rivastigmine Hexal is a medicine containing the active substance rivastigmine. It is available as capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) and as an oral solution (2 mg/ml).

What is Rivastigmine Hexal used for?

Rivastigmine Hexal 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. Rivastigmine Hexal 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 Rivastigmine Hexal used?

Treatment with Rivastigmine Hexal 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 Rivastigmine Hexal 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.

Rivastigmine Hexal should be given twice a day, with morning and evening meals. The capsules should be swallowed whole. The starting dose is 1.5 mg twice a day. In patients who tolerate this dose, it can

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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 Rivastigmine Hexal work?

The active substance in Rivastigmine Hexal, 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, 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, Rivastigmine Hexal 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 Rivastigmine Hexal been studied?

Rivastigmine Hexal has been studied in three main studies involving 2,126 patients with mild to moderately severe Alzheimer's disease. Rivastigmine Hexal was also studied in 541 patients with dementia due to Parkinson's disease. All of the studies lasted six months and compared the effects of Rivastigmine Hexal with those of placebo (a dummy treatment). The main measures of effectiveness were the change in symptoms in two main areas: 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).

An additional study in 27 patients was used to show that Rivastigmine Hexal capsules and oral solution produced similar levels of the active substance in the blood.

What benefit has Rivastigmine Hexal shown during the studies?

Rivastigmine Hexal was more effective than placebo at controlling symptoms. In the three studies of Rivastigmine Hexal in patients with Alzheimer's dementia, patients taking doses of Rivastigmine Hexal between 6 and 9 mg per day had an average increase in cognitive symptoms of 0.2 points from a baseline of 22.9 points at the start of the study, where a lower score indicates better performance. This was compared with an increase of 2.6 points from 22.5 in the patients taking placebo. For the global score, patients taking Rivastigmine Hexal had an increase in symptoms of 4.1 points, compared with 4.4 in those taking placebo.

The patients with dementia due to Parkinson's disease taking Rivastigmine Hexal capsules showed an improvement in cognitive symptoms of 2.1 points, compared with a worsening of 0.7 points in those taking placebo, from a baseline of around 24 points. The global symptom score also improved more in the patients taking Rivastigmine Hexal.

What is the risk associated with Rivastigmine Hexal?

The types of side effects seen with Rivastigmine Hexal depend on the type of dementia it is being used to treat. Overall, the most common side effects include nausea (feeling sick, seen in 38 patients in 100) and vomiting (seen in 23 patients in 100), particularly during the phase when the dose of Rivastigmine Hexal is being increased. For the full list of all side effects reported with Rivastigmine Hexal, see the package leaflet.

Rivastigmine Hexal must not be used in people who are hypersensitive (allergic) to rivastigmine, other carbamate derivatives or any of the other ingredients. It must also not be used in patients who are

suspected to have had in the past an allergic reaction called ‘allergic contact dermatitis’ to Exelon patch.

Why has Rivastigmine Hexal been approved?

The CHMP concluded that Rivastigmine Hexal has a modest effectiveness in treating the symptoms of Alzheimer’s dementia, although this does reflect an important benefit in some patients. The Committee initially concluded that for the treatment of dementia due to Parkinson’s disease, Rivastigmine Hexal’s benefits did not outweigh its risks. However, following a re-examination of this opinion, the Committee concluded that the medicine’s modest effectiveness could also be of benefit to some of these patients.

Therefore, the Committee decided that Rivastigmine Hexal’s benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Rivastigmine Hexal

The European Commission granted a marketing authorisation valid throughout the European Union for Rivastigmine Hexal on 11 December 2009. This authorisation was based on the authorisation granted to Exelon in 1998 (‘informed consent’).

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

This summary was last updated in 11-2012.