EMA/76345/2012
EMEA/H/C/001181

EPAR summary for the public

Rivastigmine 1 A Pharma

rivastigmine

This is a summary of the European public assessment report (EPAR) for Rivastigmine 1 A Pharma. 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 1 A Pharma.

What is Rivastigmine 1 A Pharma?

Rivastigmine 1 A Pharma 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 1 A Pharma used for?

Rivastigmine 1 A Pharma 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 1 A Pharma 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 1 A Pharma used?

Treatment with Rivastigmine 1 A Pharma 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 1 A Pharma 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.

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Rivastigmine 1 A Pharma 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 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 1 A Pharma work?

The active substance in Rivastigmine 1 A Pharma, 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 1 A Pharma 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 1 A Pharma been studied?

Rivastigmine 1 A Pharma has been studied in three main studies involving 2,126 patients with mild to moderately severe Alzheimer's disease. Rivastigmine 1 A Pharma 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 1 A Pharma 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 1 A Pharma capsules and oral solution produced similar levels of the active substance in the blood.

What benefit has Rivastigmine 1 A Pharma shown during the studies?

Rivastigmine 1 A Pharma was more effective than placebo at controlling symptoms. In the three studies of Rivastigmine 1 A Pharma in patients with Alzheimer's dementia, patients taking doses of Rivastigmine 1 A Pharma 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 1 A Pharma 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 1 A Pharma 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 1 A Pharma.

What is the risk associated with Rivastigmine 1 A Pharma?

The types of side effects seen with Rivastigmine 1 A Pharma 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 1 A Pharma is being increased. For the full list of all side effects reported with Rivastigmine 1 A Pharma, see the package leaflet.

Rivastigmine 1 A Pharma 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 1 A Pharma been approved?

The CHMP concluded that Rivastigmine 1 A Pharma 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 1 A Pharma'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 1 A Pharma's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Rivastigmine 1 A Pharma

The European Commission granted a marketing authorisation valid throughout the European Union for Rivastigmine 1 A Pharma on 11 December 2009. This authorisation was based on the authorisation granted to Exelon in 1998 ('informed consent').

The full EPAR for Rivastigmine 1 A Pharma 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 1 A Pharma, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.