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EPAR summary for the public

Prometax

rivastigmine

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

What is Prometax?

Prometax is a medicine containing the active substance rivastigmine. It is available as capsules (1.5, 3, 4.5 and 6 mg), as an oral solution (2 mg/ml), and as transdermal patches, which release either 4.6 , 9.5 or 13.3 mg rivastigmine across the skin over 24 hours.

What is Prometax used for?

Prometax 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.

The capsules and oral solution can also be 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 Prometax used?

Treatment with Prometax 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 give and monitor the use of Prometax 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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Prometax capsules or oral solution 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.

If the transdermal patches are used, the 4.6 mg per 24 hours patch should be used first, with the dose increased to the 9.5 mg/24 h patch after at least four weeks if the lower dose is well tolerated. The 9.5 mg/24 h patch should be used for as long as the patient benefits from it. After six months of treatment with 9.5 mg/24 hours, the doctor may increase the dose to 13.3 mg/24 hours if the patient's condition has worsened. The patches are applied to clean, dry, hairless, intact skin on the back, upper arm or chest, and are replaced every 24 hours. They should not be placed on irritated or red skin, on the thigh or abdomen (tummy), or in places where they will be rubbed by tight clothing. The patches can be worn during bathing and hot weather. The patches should not be cut into pieces. Patients can be switched from the capsules or oral solution to the patches. See the summary of product characteristics (also part of the EPAR) for detailed information.

How does Prometax work?

The active substance in Prometax, 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 substance 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, Prometax allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's dementia and dementia associated with Parkinson's disease.

How has Prometax been studied?

Prometax has been studied in mild to moderately severe Alzheimer's disease. The capsules have been studied in 2,126 patients in three main studies, and the transdermal patches in one main study involving 1,195 patients. Prometax capsules have also been studied in 541 patients with dementia due to Parkinson's disease. All of the studies lasted six months and compared the effects of Prometax 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 Prometax capsules and oral solution produced similar levels of the active substance in the blood.

What benefit has Prometax shown during the studies?

Prometax was more effective than placebo at controlling symptoms. In the three studies of Prometax capsules in patients with Alzheimer's dementia, patients taking doses of Prometax 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 Prometax capsules had in increase in symptoms of 4.1 points, compared with 4.4 in those taking placebo. The Prometax transdermal patches were also more effective than placebo in preventing dementia from getting worse.

The patients with dementia due to Parkinson's disease taking Prometax 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 Prometax.

What is the risk associated with Prometax?

The types of side effects seen with Prometax depend on the type of dementia it is being used to treat and whether the capsules, oral solution or transdermal patches are used. Overall, the most common side effects (seen in more than 1 patient in 10) include nausea (feeling sick) and vomiting, particularly during the phase when the dose of Prometax is being increased. For the transdermal patch application site reactions are the most commonly seen side effects. For the full list of all side effects reported with Prometax, see the package leaflet.

Prometax must not be used in people who are hypersensitive (allergic) to rivastigmine, other carbamate derivatives or any of the other ingredients. Prometax must also not be used in patients who are suspected to have had in the past a severe allergic reaction called 'allergic contact dermatitis' to Prometax patch.

Why has Prometax been approved?

The CHMP concluded that Prometax 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, Prometax'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 Prometax's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Prometax?

The company that makes Prometax must ensure that all doctors who intend to prescribe Prometax transdermal patch receive an information pack containing instructions to be given to patients and caregivers on how to use the patch safely as well as a reminder card for patients and caregivers that contains key information on how to use the patch and allows them to record the application and removal of patches.

Other information about Prometax

The European Commission granted a marketing authorisation valid throughout the European Union for Prometax on 4 December 1998.

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

This summary was last updated in 12-2012.