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EPAR summary for the public

Rivastigmine 3M Health Care Ltd

rivastigmine

This is a summary of the European public assessment report (EPAR) for Rivastigmine 3M Health Care Ltd. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Rivastigmine 3M Health Care Ltd.

For practical information about using Rivastigmine 3M Health Care Ltd, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rivastigmine 3M Health Care Ltd and what is it used for?

Rivastigmine 3M Health Care Ltd is a medicine that contains the active substance rivastigmine. Rivastigmine 3M Health Care Ltd is used to treat patients with mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.

Rivastigmine 3M Health Care Ltd is a 'generic medicine'. This means that Rivastigmine 3M Health Care Ltd 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.

How is Rivastigmine 3M Health Care Ltd used?

Rivastigmine 3M Health Care Ltd can only be obtained with a prescription and is available as transdermal patches, which release either 4.6 or 9.5 mg rivastigmine across the skin over 24 hours.

Treatment with Rivastigmine 3M Health Care Ltd should be started and supervised by a doctor who has experience in the diagnosis and treatment of Alzheimer's dementia. Treatment should only be started if a caregiver is available who will regularly give and monitor the use of Rivastigmine 3M Health Care Ltd 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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Treatment should be started with the 4.6-mg-per-24-hours patch, with the dose increased to the higher strength 9.5 mg/24-h patch after at least four weeks if the lower dose is well tolerated. Treatment should be continued for as long as the patient benefits from it. 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 rivastigmine capsules or oral solution to the patches. See the summary of product characteristics (also part of the EPAR) for detailed information.

How does Rivastigmine 3M Health Care Ltd work?

In patients with Alzheimer's dementia, 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).

The active substance in Rivastigmine 3M Health Care Ltd, rivastigmine works by blocking the enzymes that break down acetylcholine: acetylcholinesterase and butyrylcholinesterase. By blocking these enzymes, Rivastigmine 3M Health Care Ltd allows levels of acetylcholine to be increased in the brain, helping to reduce the symptoms of Alzheimer's dementia.

How has Rivastigmine 3M Health Care Ltd been studied?

Because Rivastigmine 3M Health Care Ltd is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Exelon. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Rivastigmine 3M Health Care Ltd?

Because Rivastigmine 3M Health Care Ltd is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Rivastigmine 3M Health Care Ltd approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Rivastigmine 3M Health Care Ltd 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 Rivastigmine 3M Health Care Ltd be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Rivastigmine 3M Health Care Ltd?

A risk management plan has been developed to ensure that Rivastigmine 3M Health Care Ltd is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rivastigmine 3M Health Care Ltd, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Rivastigmine 3M Health Care Ltd

The European Commission granted a marketing authorisation valid throughout the European Union for Rivastigmine 3M Health Care Ltd on 3 April 2014.

The full EPAR and risk management plan summary for Rivastigmine 3M Health Care Ltd 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 3M Health Care Ltd, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 04-2014.