EMA/79541/2014

Summary of the risk management plan (RMP) for Rivastigmine 3M Health Care Ltd (rivastigmine)

Overview of disease epidemiology

Alzheimer disease (AD) is the most common form of dementia. It is a progressive brain disorder that gradually affects memory, intellectual ability and behaviour and interferes with people's social interactions, jobs and daily activities. It is associated with the breakdown of nerve cells and connections in the brain.

From epidemiological studies, it is estimated that there are over three million individuals with dementia in the European Union, and of these about 70% have AD. The prevalence of AD increases with age and most cases of AD are found in individuals older than 60 years of age.

Summary of treatment benefits

Rivastigmine 3M Health Care Ltd is available as transdermal patches, which release either 4.6 or 9.5 mg rivastigmine across the skin over 24 hours. Rivastigmine 3M Health Care Ltd is a 'generic medicine' which means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Exelon. 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.

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

Unknowns relating to treatment benefits

Because Rivastigmine 3M Health Care Ltd is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's. Any uncertainties regarding its benefits are therefore also considered to be the same as for the reference medicine.

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Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
N/A		

Important potential risks

Risk	What is known
Misuse and dosing errors resulting in overdose	Misuse of the medicine and dosing errors with rivastigmine transdermal patch have resulted in serious side effects; some cases have required hospitalisation, and on rare occasions led to death. Most cases of misuse of the medicine and dosing errors have involved not removing the old patch when putting on a new one and the use of multiple patches at the same time. Patients and their caregivers must be informed of the importance of using the rivastigmine transdermal patch correctly.

Missing information

Risk	What is known
N/A	

Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet. The measures in these documents are known as routine risk minimisation measures.

The SmPC and the package leaflet for Rivastigmine 3M Health Care Ltd can be found on its EPAR page.

This medicine has special conditions and restrictions for its safe and effective use (additional risk minimisation measures). Full details on these conditions and the key elements of any educational material can be found in Annex II of the product information which is published in the EPAR page; how they are implemented in each country however will depend upon agreement between the manufacturer and the national authorities.

These additional risk minimisation measures are for the following risks:

Misuse and dosing errors resulting in overdose

Risk minimisation measure: Patient reminder card on correct use of patches
Objective and rationale: Most cases of misuse of the medicine and dosing errors have involved not removing the old patch when putting on a new one and the use of multiple patches at the same time. Patients and their caregivers must be instructed on how to use rivastigmine transdermal patches correctly in order to avoid misuse or dosing errors.
Description: Patient reminder card should include the following: • Instruction for use o take off the previous patch before putting ONE new patch on o use only one patch per day o do not cut the patch into pieces o press the patch firmly in place for at least 30 seconds using the palm of the hand • Illustration showing proper patch application and body locations • Patient medication record with space for 60 days record including: o a column which indicates the application date o a column which indicates the day of the week o a column which indicates if the previous patch has been taken off o a column which indicates where the patch has been applied

Planned post-authorisation development plan

No post-authorisation safety or efficacy studies are ongoing or are planned to be conducted for rivastigmine.

Summary of changes to the risk management plan over time

Major changes to the Risk Management Plan over time

This summary was last updated in 02-2014.