Part VI: Summary of the risk management plan

Summary of risk management plan for Rivastor (rivastigmine)

This is a summary of the risk management plan (RMP) for Rivastor. The RMP details important risks of Rivastor, how these risks can be minimized, and how more information will be obtained about Rivastor's risks and uncertainties (missing information).

Rivastor's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivastor should be used.

Important new concerns or changes to the current ones will be included in updates of Rivastor's RMP.

I. The medicine and what it is used for

Rivastor is authorised for symptomatic treatment of mild to moderately severe Alzheimer’s dementia (see SmPC for the full indication). It contains rivastigmine as the active substance and it is administered as transdermal patch.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Rivastor, together with measures to minimise such risks and the proposed studies for learning more about Rivastor's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of Rivastor, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Rivastor are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Rivastor. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• Medication error and misuse
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Medication error and misuse	
Evidence for linking the risk to the medicine	Overdose with rivastigmine transdermal patch resulting from misuse/dosing errors (application of multiple patches at a time) has been reported in the post-marketing setting and rarely in clinical trials. Misuse of the medicinal product and dosing errors with rivastigmine transdermal patch have resulted in serious adverse reactions; some cases have required hospitalisation, and rarely led to death.
Risk factors and risk groups	Most cases of misuse of the medicinal product 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 important administration instructions for rivastigmine transdermal patch. Similar to any treatment initiated in patients with dementia, therapy with rivastigmine should only be started if a caregiver is available to regularly administer and monitor the treatment.
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.2, 4.4, 4.9, 6.2, 6.6. PL section 3. Prescription only medicine. Additional risk minimisation measures: Information pack

II.C Post-authorisation development plan

There are no studies required for Rivastor.