Part VI: Summary of the risk management plan

Summary of risk management plan for Rivastigmine-containing transdermal patches (rivastigmine)

This is a summary of the risk management plan (RMP) for Rivastigmine-containing transdermal patches. The RMP details important risks of Rivastigmine-containing transdermal patches and how these risks can be minimised.
Rivastigmine-containing transdermal patches´ summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivastigmine-containing transdermal patches should be used.
Important new concerns or changes to the current ones will be included in updates of Rivastigmine-containing transdermal patches´ RMP.

I. The medicine and what it is used for

Rivastigmine-containing transdermal patches are 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 minimize or further characterize the risks

Important risks of Rivastigmine-containing transdermal patches, together with measures to minimise such risks and the proposed studies for learning more about Rivastigmine-containing transdermal patches´ risks, are outlined below.
Measures to minimize 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.
In the case of Rivastigmine-containing transdermal patches 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, including PSUR assessment 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 Rivastigmine-containing transdermal patches are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Rivastigmine-containing transdermal patches. 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.

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

II.B: Summary of important risks

Important identified risk: Medication misuse	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.4, 4.9 and 6.2. PL section 3. Recommendation for symptomatic treatment in overdose in SmPC section 4.9. Prescription only medicine. Additional risk minimisation measures: Information pack

Important identified risk: Medication error	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.4, 4.9, 6.2 and 6.6. PL section 3. Recommendation for symptomatic treatment in overdose in SmPC section 4.9. Prescription only medicine. Additional risk minimisation measures: Information pack

II.C: Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Rivastigmine-containing transdermal patches.

II.C.2. Other studies in post-authorization development plan

There are no studies required for Rivastigmine-containing transdermal patches.