Summary of the risk management plan for Prometax (rivastigmine)

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

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

This summary of the RMP for Prometax should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Prometax is indicated for:

1. for the symptomatic treatment of mild to moderately severe Alzheimer's dementia [AD]
2. for the symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease [PDD] (not with the patch)

It contains rivastigmine as the active substance and it is given as a capsule or liquid by oral route of administration, also known as in the mouth, or it is given as a patch by transdermal route of administration, also known as to the skin.

Further information about the evaluation of Prometax's benefits can be found in Prometax's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to Prometax's EPAR summaries: https://www.ema.europa.eu/en/medicines/human/EPAR/Exelon and https://www.ema.europa.eu/en/medicines/human/EPAR/Prometax.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Prometax, together with measures to minimize such risks and the proposed studies for learning more about Prometax's 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 authorized 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 and SmPC Section 4.2, Section 4.4, Section 4.9, PL Section 2, Section 3 constitute **routine risk minimization measures**.

In the case of Prometax, these measures are supplemented with **additional risk minimization measures** mentioned under relevant important risks, as below:

- the Patient Reminder Card

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Prometax are risks that need special risk management activities to further investigate or minimize 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 Prometax. 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).

Table 1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	• Medication misuse (patch only) • Medication errors (patch only)
Important potential risks	• None
Missing information	• None

II B: Summary of important risks

Table 2 Important identified risk: Medication misuse (patch only)

Evidence for linking the risk to the medicine	No clinical studies have been conducted to investigate the abuse potential in humans with rivastigmine, albeit, misuse for illegal purposes. Studies in rhesus monkeys strongly suggest that at relevant doses, rivastigmine did not have any reinforcing capacity or ability to cause physical dependence. The misunderstanding with patch and/or rivastigmine formulation-switching instructions is the attributable evidence
Risk factors and risk groups	Patients or caregivers (an applicant) who cannot understand or strictly follow instructions on the proper use of patch and application of patch. Patients who do not receive adequate instructions from the physician (prescriber).
Risk minimization measures	**Routine risk minimization measures** SmPC Section 4.2, Section 4.4, Section 4.9 PL Section 2, Section 3 Limited pack size: packaging 1 patch/sachet **Additional risk minimization measures** Patient Reminder Card

Table 3 Important identified risk: Medication errors (patch only)

Evidence for linking the risk to the medicine	No clinical studies have been conducted to investigate the abuse potential in humans with rivastigmine, albeit, misuse for illegal purposes. Studies in rhesus monkeys strongly suggest that at relevant doses, rivastigmine did not have any reinforcing capacity or ability to cause physical dependence. The misunderstanding with patch and/or rivastigmine formulation-switching instructions is the attributable evidence.
Risk factors and risk groups	Patients or caregivers (an applicant) who cannot understand or strictly follow instructions on the proper use of patch and application of patch. Patients who do not receive adequate instructions from the physician (prescriber).
Risk minimization measures	**Routine risk minimization measures** SmPC Section 4.2. Section 4.4, Section 4.9 PL Section 2, Section 3 Limited pack size: packaging 1 patch/sachet **Additional risk minimization measures** Patient Reminder Card

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 of specific obligation for Prometax.

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

There are no studies required for Prometax.