NOVARTIS

Regulatory Affairs

Drug generic name

Summary of the *EU* Safety Risk Management Plan

Active substance(s) (INN or common name):	*Rivastigmine*
Product(s) concerned (brand name(s)):	*Exelon®*
Document status:	*Final*
Version number of the RMP Public Summary: *(aligned with corresponding RMP version)*	*11.0*
Date of final sign off of the RMP Public Summary *(this is referring to this document)*	*23-08-2023*

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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of “Excelon®, Kapseln” is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of “Excelon®, Kapseln” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Novartis Pharma Schweiz AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Excelon®, Kapseln”.

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Summary of the risk management plan for Exelon (rivastigmine)
This is a summary of the risk management plan (RMP) for Exelon. The RMP details important risks of Exelon, how these risks can be minimized, and how more information will be obtained about Exelon's risks.
Exelon's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Exelon should be used.
This summary of the RMP for Exelon 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 Exelon's RMP.

I. The medicine and what it is used for
Exelon is authorized 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 Exelon's benefits can be found in Exelon's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to Exelon'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 Exelon, together with measures to minimize such risks and the proposed studies for learning more about Exelon'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 the Exelon patch, these measures are supplemented with an **additional risk minimization measure** 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 Exelon 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 Exelon. 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 Excelon.

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

There are no studies required for Exelon.