Rivastigmine-containing transdermal patches

Active substance(s) (INN or common name):	Rivastigmine
Version number of the RMP on which this summary is based:	v.0.4
Name of Marketing Authorization Holder:	Luye Pharma Switzerland AG
Date of this RMP Public Summary:	01 March 2024

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 "Rivastigmine-containing transdermal patches" 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 "Rivastigmine-containing transdermal patches" in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "Luye Pharma Switzerland AG" is fully responsible for the accuracy and correctness of the content of the published summary RMP of "Rivastigmine-containing transdermal patches".

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 minimise or further characterise 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	<u>Routine risk minimisation measures</u> 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. Outer package labelling: "Replace the transdermal patch twice a week, at the latest after 4 days." <u>Additional risk minimisation measures:</u> Information pack

Important identified risk: Medication error	
Risk minimisation measures	<u>Routine risk minimisation measures</u> 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. Outer package labelling: "Replace the transdermal patch twice a week, at the latest after 4 days." <u>Additional risk minimisation measures:</u> 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.