

Part VI: Summary of the risk management plan

Summary of risk management plan for Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster (rivastigmine)

This is a summary of the risk management plan (RMP) for Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster. The RMP details important risks of Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster, how these risks can be minimized, and how more information will be obtained about Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster's risks and uncertainties (missing information).

Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster's summary of product characteristics (SmPCs) and its package leaflet (PLs) give essential information to healthcare professionals (HCPs) and patients on how Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden

transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster should be used.

Important new concerns or changes to the current ones will be included in updates of Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster RMP.

I. The medicine and what it is used for

Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster are authorised for the symptomatic treatment of mild to moderately severe Alzheimer's dementia.

It contains rivastigmine as an active substance and it is given by transdermal route.

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

Important risks of Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster together with measures to minimize such risks and the proposed studies for learning more about Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster's 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 minimisation measures*.

In the case of the Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster these measures are supplemented with *additional risk minimisation measure* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster 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 Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster. 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 misuse (patch only)
	Medication errors (patch only)
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product.

Important identified risk: Medication misuse (patch only)	
Risk minimisation measures	<p>Routine risk minimisation measures</p> <p>SmPC sections 4.2, 4.4 and 4.9 PL sections 2 and 3 Legal status: Prescription only</p> <p>Additional risk minimisation measures:</p> <p>Patient reminder card</p>

Important identified risk: Medication errors (patch only)	
Risk minimisation measures	<p>Routine risk minimisation measures</p> <p>SmPC sections 4.2, 4.4 and 4.9 PL sections 2 and 3 Legal status: Prescription only</p> <p>Additional risk minimisation measures:</p> <p>Patient reminder card</p>

II.C. Post-authorisation development plan

II.C.1 Studies which are conditions of the Marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster.

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

There are no studies required for Rivastigmin Sandoz GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin Sandoz GmbH 13,3 mg/24 Stunden transdermales Pflaster; Rivastigmin 1A Pharma GmbH 4,6 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 9,5 mg/24 Stunden transdermales Pflaster, Rivastigmin 1A Pharma GmbH 13,3 mg/24 Stunden transdermales Pflaster; Nimgista 4,6 mg/24 Stunden transdermales Pflaster, Nimgista 9,5 mg/24 Stunden transdermales Pflaster, Nimgista 13,3 mg/24 Stunden transdermales Pflaster.