PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for STRIVALON (Rivastigmine)

This is a summary of the risk management plan (RMP) for STRIVALON. The RMP details important risks of STRIVALON, how these risks can be minimised, and how more information will be obtained about STRIVALON risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

STRIVALON is authorised for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

It contains Rivastigmine as the active substance and it is given by a transdermal patch.

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

Important risks of STRIVALON, together with measures to minimise such risks and the proposed studies for learning more about STRIVALON's risks, are outlined below.

Measures to minimise 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 minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of STRIVALON, 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 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 STRIVALON 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 STRIVALON. 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 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 section 4.2, 4.4 and 4.9* *PL section 2 and 3* Pack size: *Each sachet contains a transdermal patch.* Legal status: *Prescription medicine* Additional risk minimisation measures: *Patient Reminder Card*
Important identified risk: Medication error	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2, 4.4 and 4.9* *PL section 2 and 3* Pack size: *Each sachet contains a transdermal patch.* Legal status: *Prescription medicine* Additional risk minimisation measures: *Patient Reminder Card*

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 STRIVALON.

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

There are no studies required for STRIVALON.