## PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

### Summary of risk management plan for Silarosa 10 mg/ml oral solution (lisdexamfetamine)

This is a summary of the risk management plan (RMP) for Silarosa 10 mg/mL oral solution. The RMP details important risks of Silarosa 10 mg/mL oral solution how these risks can be minimised, and how more information will be obtained about Silarosa 10 mg/mL oral solution risks and uncertainties (missing information).
Silarosa 10 mg/mL oral solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Silarosa 10 mg/mL oral solution should be used.
Important new concerns or changes to the current ones will be included in updates of Silarosa 10 mg/mL oral solution's RMP.

### *I. The medicine and what it is used for*

Silarosa is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate.
Treatment must be under the supervision of a specialist in childhood and/or adolescent behavioural disorders. Diagnosis should be made according to DSM criteria or the guidelines in ICD and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptom.
The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources.
A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired.
Silarosa is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion.
Appropriate educational placement is essential, and psychosocial intervention is generally necessary. The use of Silarosa should always be used in this way according to the licensed indication.

It contains lisdexamfetamine as the active substance and it is given by oral administration.

### *II. Risks associated with the medicine and activities to minimise or further characterise the risks*

Important risks of Silarosa 10 mg/mL oral solution, together with measures to minimise such risks and the proposed studies for learning more about lisdexamfetamine 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 Silarosa 10 mg/mL oral solution, 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 so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.
If important information that may affect the safe use of Silarosa 10 mg/mL oral solution is not yet available, it is listed under 'missing information' below.

### *II.A List of important risks and missing information*

Important risks of Silarosa 10 mg/mL oral solution are risks that need special risk management activities to further investigate or minimise 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 Silarosa 10 mg/mL oral solution. 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 | Intentional drug misuse, abuse and diversion |
| Important potential risks | None |
| Missing information | None |

### *II.B Summary of important risks*

| **Important identified risk: Intentional drug misuse, abuse and diversion** | |
|---|---|
| Risk minimisation measures | <u>Routine risk minimisation measures:</u><br>*Covered under the following section of SmPC and PL:*<br>• Section 4.2 of SmPC: Patients should be monitored for the risk of diversion, misuse, and abuse<br>• Section 4.4 of SmPC: Consistent with other stimulants, the potential for abuse, misuse or diversion of lisdexamfetamine should be considered prior to prescribing.<br>• Advice to patients provided in PL in section 2.<br><br><u>Other routine risk minimisation measures</u> |

| | |
|---|---|
| | Legal status: Prescription only medicine. It is prescribed only by doctors who have experience in treating people with behaviour problems.<br><br><u>Additional risk minimization measures:</u><br>Educational tools, in the form of Physician's guide to prescribing.<br>• Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy<br>• Prescriber Checklist 1: Lisdexamfetamine dimesylate checklist before prescribing<br>• Prescriber Checklist 2: Checklist for the ongoing monitoring of lisdexamfetamine dimesylate therapy<br>• Carer information – Potential for non-medical use and diversion of prescription stimulant medications |

## *II.C Post-authorisation development plan*

### *II.C.1 Studies which are conditions of the marketing authorisation*

There are no studies that are conditions of the marketing authorization or specific obligation of Silarosa 10 mg/mL oral solution.

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

There are no studies required for Silarosa 10 mg/mL oral solution.