Part VI: Summary of the risk management plan

Summary of risk management plan for Lisdexamfetamin reddy 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg hårda kapslar (Lisdexamfetamine)

This is a summary of the risk management plan (RMP) for Lisdexamfetamin reddy 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg hårda kapslar (Hereinafter referred to as "Lisdexamfetamine Reddy"). The RMP details important risks of Lisdexamfetamine Reddy, how these risks can be minimised and how more information will be obtained about Lisdexamfetamine Reddy's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Lisdexamfetamine Reddy's RMP.

I. The medicine and what it is used for

Lisdexamfetamine Reddy is authorised for the following indications:

- 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.
- As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults with pre-existing symptoms of ADHD in childhood

It contains lisdexamfetamine dimesylate as the active substance and is given orally.

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

Important risks of Lisdexamfetamine Reddy, together with measures to minimise such risks and the proposed studies for learning more about Lisdexamfetamine Reddy'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 Lisdexamfetamine Reddy, 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*.

If important information that may affect the safe use of Lisdexamfetamine Reddy is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	• Intentional drug misuse, abuse and diversion • Growth retardation and developmental delay in children and adolescents • Psychosis/Mania • Hostility/Aggression • Depression
Important potential risks	• Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death) • Cerebrovascular disorders (ischaemic and haemorrhagic stroke) • Syncope • Suicidality • Off-label use • Neonatal effects on growth (via lactation)
Missing information	• Safety in pregnant women • Safety in the elderly • Long-term safety (cardiovascular and cerebrovascular effects) in adults

II.B Summary of important risks

Important identified risks:	
Intentional drug misuse, drug abuse and diversion	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.1, 4.2 and 4.4 • PIL section 2 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate

	• Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment • Potential for non-medical use and diversion of prescription stimulant medications leaflet
Growth retardation and developmental delay in children and adolescents	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.2, 4.4 and 4.8 • PIL section 2 and 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Psychosis/Mania	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.4 and 4.8 • PIL section 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Hostility/Aggression	
Risk minimisation measures	Routine risk minimisation measures

	• SmPC section 4.4 and 4.8 • PIL section 2 and 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Depression	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.2, 4.4 and 4.8 • PIL section 2 and 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Important potential risks	
Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.4 and 4.8 • PIL section 2 and 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate

	• Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.4 and 4.8 • PIL section 2 and 4 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Syncope	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.4 and 4.8 • PIL section 4 Prescription only medicine. Additional risk minimisation measures • None
Suicidality	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.4 • PIL section 2 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate

	• Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Off-label use	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.2 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment • Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Neonatal effects on growth (via lactation)	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.6 Prescription only medicine. Additional risk minimisation measures • None
Missing information	
Safety in pregnant women	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.6 • PIL section 2 Prescription only medicine. Additional risk minimisation measures • Prescriber checklist before prescribing lisdexamfetamine dimesylate • Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment

	• Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
Safety in the elderly	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.2 Prescription only medicine. Additional risk minimisation measures • None
Long-term safety (cardiovascular and cerebrovascular effects) in adults	
Risk minimisation measures	Routine risk minimisation measures • SmPC section 4.2 Prescription only medicine. Additional risk minimisation measures • None

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 Lisdexamfetamine Reddy.

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

There are no studies required for Lisdexamfetamine Reddy.