Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for LISDEXAMFETAMINE 20, 30, 40, 50, 60 AND 70 MG CAPSULES, HARD

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

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

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

I. The Medicine and What It is used for

Lisdexamfetamine is authorised as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) (see SmPC for the full indication). It contains lisdexamfetamine as the active substance and it is taken orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

Table 8: Summary of Safety Concerns

List of important risks and missing information	
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

Table 9: Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important identified risk: Intentional drug misuse, drug abuse and diversion	
Risk minimisation measures	Routine risk minimisation measures Section 4.2 and 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important identified risk: Growth retardation and developmental delay in children and adolescents	
Risk minimisation measures	Routine risk minimisation measures Section 4.2, 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important identified risk: Psychosis/Mania	
Risk minimisation measures	Routine risk minimisation measures Section 4.2, 4.3, 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important identified risk: Hostility/Aggression	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important identified risk: Depression	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important potential risk: Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)	
Risk minimisation measures	Routine risk minimisation measures Section 4.2, 4.3, 4.4, 4.8 and 4.9 of the SmPC Additional risk minimisation measures Educational tools.

Important potential risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
Risk minimisation measures	Routine risk minimisation measures Section 4.2, 4.3 and 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important potential risk: Suicidality	
Risk minimisation measures	Routine risk minimisation measures Section 4.2 and 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important potential risk: Syncope	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures None
Important potential risk: Off-label use	
Risk minimisation measures	Routine risk minimisation measures Section 4.2 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.
Important potential risk: Neonatal Effects on Growth (via Lactation)	
Risk minimisation measures	Routine risk minimisation measures Section 4.6 of the SmPC Prescription only medicine. Additional risk minimisation measures None
Missing information: Safety in pregnant women	
Risk minimisation measures	Routine risk minimisation measures Section 4.6 of the SmPC Prescription only medicine. Additional risk minimisation measures Educational tools.

Missing information: Safety in the elderly	
Risk minimisation measures	Routine risk minimisation measures Section 4.2 of the SmPC Prescription only medicine. Additional risk minimisation measures None
Missing information: Long-term safety (cardiovascular and cerebrovascular effects) in adults	
Risk minimisation measures	Routine risk minimisation measures Section 4.2 of the SmPC 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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Lisdexamfetamine.