Part VI: Summary of the risk management plan

Summary of risk management plan for Lisfaveen 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg capsule, hard

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

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

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

I. The medicine and what it is used for

Lisfaveen 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 dibesylate 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 Lisfaveen, together with measures to minimise such risks and the proposed studies for learning more about Lisfaveen´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 Lisfaveen, 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 Lisfaveen 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

Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important identified risks: Intentional drug misuse, abuse and diversion	
Risk minimisation measures	Routine risk minimisation measures Section 4.1, 4.2 and 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures

	Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy and patient guide.
Important identified risks: 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 Chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy and patient guide
Important identified risks: Psychosis/Mania	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy
Important identified risks: 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 Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy
Important identified risks: Depression	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine Additional risk minimisation measures Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy
Important potential risks: Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)	

Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine Additional risk minimisation measures Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy
Important potential risks: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine Additional risk minimisation measures Prescriber checklist, chart for the ongoing monitoring of lisdexamfetamine dibesylate therapy
Important potential risks: Syncope	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 and 4.8 of the SmPC Prescription only medicine. Additional risk minimisation measures None
Important potential risks: Suicidality	
Risk minimisation measures	Routine risk minimisation measures Section 4.4 of the SmPC Prescription only medicine. Additional risk minimisation measures Prescriber checklist
Important potential risks: Off-label use	
Risk minimisation measures	Routine risk minimisation measures Prescription only medicine. Additional risk minimisation measures Prescriber checklist
Important potential risks: 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 Prescriber checklist.
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 Lisfaveen.

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

There are no studies required for Lisfaveen.