Summary of risk management plan for LISDEXAMFETAMINE ORION 20 MG, 30 MG, 40 MG 50 MG, 60 MG AND 70 MG CAPSULES, HARD LISDEXAMFETAMINE DIMESYLATE
Orion Corporation

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

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

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

I. The medicine and what it is used for

Lisdexamfetamin Orion is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD):

- for children and young people between ages of 6 and 18 who have previously taken a methylphenidate treatment that inadequately treated their ADHD.
- for adults who have had ADHD since childhood (see SmPC for the full indication).

It contains lisdexamfetamine dimesylate as the active substance and it is given by mouth.

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

Important risks of Lisdexamfetamin Orion, together with measures to minimise such risks and the proposed studies for learning more about Lisdexamfetamin Orion'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 Lisdexamfetamin Orion, 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 analyzed, 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 Lisdexamfetamin Orion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Lisdexamfetamin Orion 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 Lisdexamfetamin Orion. 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 • 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

The safety information in the proposed product Information is aligned to the reference medicinal product.

Important identified risk: Intentional drug misuse, abuse and diversion	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.2 and 4.4 and PL section 2. Prescription only medicine Additional risk minimization measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2 Carer information

Important Identified risk: Growth retardation and developmental delay in children and adolescents	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.2, 4.4 and 4.8. Prescription only medicine Additional risk minimization measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important Identified risk: Psychosis/Mania	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4 and 4.8 and PL section 4. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2

Important Identified risk: Hostility/Aggression	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.3, 4.4 and 4.8 and PL sections 2 and 4. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important Identified risk: Depression	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.2, 4.4 and 4.8 and PL sections 2 and 4. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important potential risk: Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.2, 4.4 and 4.8 and PL sections 2 and 4. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important potential risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
Risk minimisation measures	Routine risk minimisation measures:

	Information in SmPC section 4.4. Prescription only medicine <u>Additional risk minimisation measures:</u> Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important potential risk: Syncope	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Information in SmPC sections 4.4 and 4.8. Prescription only medicine <u>Additional risk minimisation measures:</u> None
Important potential risk: Suicidality	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Information in SmPC section 4.4 and PL section 2. Prescription only medicine <u>Additional risk minimisation measures:</u> Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Important potential risk: Off-label use	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Prescription only medicine <u>Additional risk minimisation measures:</u> Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2

Important potential risk: Neonatal effects on growth (via lactation)	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC section 4.6 and PL section 2. Prescription only medicine Additional risk minimization measures: None
Missing information: Safety in pregnant women	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC section 4.6 and PL section 2. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy Prescriber Checklist 1 Prescriber Checklist 2
Missing information: Safety in the elderly	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC section 4.2. 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: Information in SmPC section 4.2. Prescription only medicine Additional risk minimisation measures: Chart for the ongoing monitoring of lisdexamfetamine dimesylate therapy

	Prescriber Checklist 1 Prescriber Checklist 2

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 Lisdexamfetamin Orion.

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

There are no studies required for Lisdexamfetamin Orion.