Part VI: Summary of the risk management plan

Summary of risk management plan for Eldefab 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 Eldefab. The RMP details important risks of Eldefab, how these risks can be minimised and how more information will be obtained about Eldefab' risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

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

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	<u>Routine risk minimisation measures</u> SmPC sections 4.1, 4.2 and 4.4. PIL section 2 and 3. Legal status: Prescription only medicinal product <u>Additional risk minimisation measures:</u> 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

Important identified risk: Growth retardation and developmental delay in children and adolescents	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.4 and 4.8 Patient leaflet sections 2 and 4. Legal status: Prescription only medicinal product 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 identified risk: Psychosis/Mania	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Patient leaflet section 4. Legal status: Prescription only medicinal product 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 identified risk: Hostility/Aggression	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Patient leaflet sections 2 and 4. Legal status: Prescription only medicinal product Additional risk minimisation measures: Prescriber checklist before prescribing lisdexamfetamine dimesylate

Important identified risk: Hostility/Aggression	
	Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment

Important identified risk: Depression	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.4 and 4.8 Patient leaflet section 2 and 4. Legal status: Prescription only medicinal product 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 risk: Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Patient leaflet sections 2 and 4. Legal status: Prescription only medicinal product 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 risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Patient leaflet sections 2 and 4.

Important potential risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)	
	Legal status: Prescription only medicinal product <u>Additional risk minimisation measures:</u> 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 risk: Syncope	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC sections 4.4 and 4.8 Patient leaflet section 4. Legal status: Prescription only medicinal product <u>Additional risk minimisation measures:</u> None

Important potential risk: Suicidality	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC section 4.4 Patient leaflet section 2. Legal status: Prescription only medicinal product <u>Additional risk minimisation measures:</u> 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 risk: Off-label use	
Risk minimisation measures	<u>Routine risk minimisation measures</u> None

Important potential risk: Off-label use	
	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

Important potential risk: Neonatal effects on growth (via lactation)	
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.6 Patient leaflet section 2 Legal status: Prescription only medicinal product 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 Legal status: Prescription only medicinal product 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

Missing information: Safety in the elderly	
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.2 Legal status:

Missing information: Safety in the elderly	
	Prescription only medicinal product Additional risk minimisation measures: None

Missing information: Long-term safety (cardiovascular and cerebrovascular effects) in adults	
Long-term safety (cardiovascular and cerebrovascular effects) in adults	Routine risk minimisation measures SmPC section 4.2 Legal status: Prescription only medicinal product 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 Eldefab.

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

There are no studies required for Eldefab.