

## Part VI: Summary of the risk management plan

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

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

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

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

### I. The medicine and what it is used for

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

| Summary of safety concerns |                                                                                                                                                                                                                                                                         |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            | Growth retardation and developmental delay in children and adolescents<br>Psychosis/Mania<br>Hostility/Aggression<br>Depression                                                                                                                                         |
| Important potential risks  | Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death)<br>Cerebrovascular disorders (ischaemic and haemorrhagic stroke)<br>Syncope<br>Suicidality<br>Off-label use<br>Neonatal effects on growth (via lactation) |
| Missing information        | Safety in pregnant women<br>Safety in the elderly<br>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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
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| Risk minimisation measures                                              | <u>Routine risk minimisation measures</u><br>SmPC sections 4.1, 4.2 and 4.4.<br>PIL section 2 and 3.<br>Legal status:<br>Prescription only medicinal product<br><u>Additional risk minimisation measures:</u><br>Prescriber checklist before prescribing lisdexamfetamine dimesylate<br>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment<br>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment<br>Potential for non-medical use and diversion of prescription stimulant medications leaflet |

Important identified risk: Growth retardation and developmental delay in children and adolescents

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| Risk minimisation measures                      | <u>Routine risk minimisation measures</u><br>SmPC sections 4.2, 4.4 and 4.8<br>Patient leaflet sections 2 and 4.<br>Legal status:<br>Prescription only medicinal product<br><u>Additional risk minimisation measures:</u><br>Prescriber checklist before prescribing lisdexamfetamine dimesylate<br>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment<br>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment |
| Important identified risk: Psychosis/Mania      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Risk minimisation measures                      | <u>Routine risk minimisation measures</u><br>SmPC sections 4.4 and 4.8<br>Patient leaflet section 4.<br>Legal status:<br>Prescription only medicinal product<br><u>Additional risk minimisation measures:</u><br>Prescriber checklist before prescribing lisdexamfetamine dimesylate<br>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment<br>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment             |
| Important identified risk: Hostility/Aggression |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Risk minimisation measures                      | <u>Routine risk minimisation measures</u><br>SmPC sections 4.4 and 4.8<br>Patient leaflet sections 2 and 4.<br>Legal status:<br>Prescription only medicinal product<br><u>Additional risk minimisation measures:</u><br>Prescriber checklist before prescribing lisdexamfetamine dimesylate                                                                                                                                                                               |
| Important identified risk: Hostility/Aggression |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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|                                                                                                                                         | <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p>                                                                                                                                                                                                                                                                                                                                |
| Important identified risk: Depression                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Risk minimisation measures                                                                                                              | <p><u>Routine risk minimisation measures</u></p> <p>SmPC sections 4.2, 4.4 and 4.8</p> <p>Patient leaflet section 2 and 4.</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p> |
| Important potential risk: Serious cardiovascular events (including arrhythmias, ischaemic cardiac events, cardiomyopathy, sudden death) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Risk minimisation measures                                                                                                              | <p><u>Routine risk minimisation measures</u></p> <p>SmPC sections 4.4 and 4.8</p> <p>Patient leaflet sections 2 and 4.</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p>     |
| Important potential risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Risk minimisation measures                                                                                                              | <p><u>Routine risk minimisation measures</u></p> <p>SmPC sections 4.4 and 4.8</p>                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Important potential risk: Cerebrovascular disorders (ischaemic and haemorrhagic stroke)                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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|                                         | <p>Patient leaflet sections 2 and 4.</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p> |
| Important potential risk: Syncope       |                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Risk minimisation measures              | <p><u>Routine risk minimisation measures</u></p> <p>SmPC sections 4.4 and 4.8</p> <p>Patient leaflet section 4.</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>None</p>                                                                                                                                                                      |
| Important potential risk: Suicidality   |                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Risk minimisation measures              | <p><u>Routine risk minimisation measures</u></p> <p>SmPC section 4.4</p> <p>Patient leaflet section 2.</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Chart for on oin monitorin durin lisdexamfetamine dimes late treatment</p>                                  |
| Important potential risk: Off-label use |                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Risk minimisation measures              | <p><u>Routine risk minimisation measures</u></p> <p>None</p> <p><u>Additional risk minimisation measures:</u></p>                                                                                                                                                                                                                                                                                                         |

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| Important potential risk: Off-label use                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                      | <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p> <p>Potential for non-medical use and diversion of prescription stimulant medications leaflet</p>                                                                                                                   |
| Important potential risk: Neonatal effects on growth (via lactation) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Risk minimisation measures                                           | <p><u>Routine risk minimisation measures</u></p> <p>SmPC section 4.6</p> <p>Patient leaflet section 2</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>None</p>                                                                                                                                                                                                                                     |
| Missing information: Safety in pregnant women                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Risk minimisation measures                                           | <p><u>Routine risk minimisation measures</u></p> <p>SmPC section 4.6</p> <p>PIL section 2</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>Prescriber checklist before prescribing lisdexamfetamine dimesylate</p> <p>Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment</p> <p>Chart for the ongoing monitoring of lisdexamfetamine dimesylate treatment</p> |
| Missing information: Safety in the elderly                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Risk minimisation measures                                           | <p><u>Routine risk minimisation measures</u></p> <p>SmPC section 4.2</p> <p>Legal status:</p>                                                                                                                                                                                                                                                                                                                                                                                  |
| Missing information: Safety in the elderly                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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|                                                                                              | <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>None</p>                                                                                               |
| Missing information: Long-term safety (cardiovascular and cerebrovascular effects) in adults |                                                                                                                                                                                                           |
| <p>Long-term safety (cardiovascular and cerebrovascular effects) in adults</p>               | <p><u>Routine risk minimisation measures</u></p> <p>SmPC section 4.2</p> <p>Legal status:</p> <p>Prescription only medicinal product</p> <p><u>Additional risk minimisation measures:</u></p> <p>None</p> |

## 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 Lysmi.

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

There are no studies required for Lysmi.