Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Melatonin 1 mg/mL Oral solution

This is a summary of the Risk Management Plan (RMP) for Melatonin 1 mg/mL Oral solution. The RMP details important risks of Melatonin 1 mg/mL Oral solution, how these risks can be minimised, and how more information will be obtained about Melatonin 1 mg/mL Oral Solution risks and uncertainties (missing information).

Melatonin 1 mg/mL Oral Solution's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Melatonin 1 mg/mL Oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of Melatonin 1 mg/mL Oral Solution RMP.

I. The medicine and what it is used for

Melatonin 1 mg/mL Oral solution is indicated for:

- Short-term treatment of jet-lag in adults.
- Sleep onset insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD), where sleep hygiene measures have been insufficient.

It contains melatonin as the active substance and it is taken by the oral route of administration.

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

Important risks of Melatonin 1 mg/mL Oral solution, together with measures to minimise such risks and the proposed studies for learning more about Melatonin 1 mg/mL Oral solution 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 PL 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, 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 Melatonin 1 mg/mL Oral solution 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 Melatonin 1 mg/mL Oral solution. 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 risk(s)	• None
Important potential risk(s)	• None
Missing information	• None

II.B. Summary of important risk

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

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 Melatonin1 mg/mL Oral solution.

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

There are no studies required for Melatonin 1 mg/mL Oral solution.