Part VI: Summary of the risk management plan
Summary of risk management plan for Melatonin Orion (melatonin)

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

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

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

I. The medicine and what it is used for

Melatonin Orion contains melatonin as the active substance and it is given by mouth.

Melatonin Orion is indicated for:

With or without prescription

• Short term treatment of jet lag in adults.

With prescription only

• Insomnia in children and adolescents aged 6–17 years with ADHD where sleep hygiene measures have been insufficient.

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

Important risks of Melatonin Orion, together with measures to minimise such risks and the proposed studies for learning more about Melatonin 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 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*.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

There are no studies required for Melatonin Orion.