PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Melatonin 2 mg prolonged-release tablets:

This is a summary of the risk management plan (RMP) for melatonin 2 mg prolonged-release tablets. The RMP details important risks of melatonin, how these risks can be minimized and how more information will be obtained about melatonin's risks and uncertainties (missing information).

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

I. The medicine and what it's used for:

Melatonin prolonged-release tablets is authorised for the short-term treatment as monotherapy for primary insomnia characterised by poor quality of sleep-in patients who are aged 55 or over.

It contains Melatonin as the active substance, and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of melatonin, together with measures to minimize such risks and the proposed studies for learning more about melatonin's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and the summary of product characteristics (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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of melatonin are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered.

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. 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	• None
Important Potential Risks	• Confusion • Hallucinations • Dyspnoea

List of Important risks and missing information	
Missing Information	• Use in pregnancy/lactation

II.B. Summary of important risks

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 melatonin.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for melatonin.