

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Melatonin Viatris (Melatonin)

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

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

I. The Medicine and What it is Used For

Melatonin Viatris is authorised as monotherapy for the short-term treatment of 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 as 2 mg prolonged-release tablets.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Melatonin Viatris, together with measures to minimise such risks and the proposed studies for learning more about Melatonin Viatris '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 public (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 events 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 Melatonin Viatris is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Melatonin Viatris are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Viatris. 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.

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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/use in special patient populations etc.);

Table 4: Part VI.1- Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	<ul style="list-style-type: none">• None
Important Potential Risks	<ul style="list-style-type: none">• Confusion• Hallucinations• Dyspnoea
Missing Information	<ul style="list-style-type: none">• 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 Viatris.

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

There are no studies required for Melatonin Viatris.