# Summary of risk management plan for Melatonin Pharma Nord (Melatonin)

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

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

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

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

Melatonin Pharma Nord is authorised for short-term treatment of jet-lag in adults (see SmPC for the full indication). It contains melatonin as the active substance and it is given by orally.

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

Important risks of Melatonin Pharma Nord, together with measures to minimise such risks and the proposed studies for learning more about Melatonin Pharma Nord'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, including PSUR assessment - 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 Pharma Nord is not yet available, it is listed under ‘missing information’ below.

## *II.A List of important risks and missing information*

Important risks of Melatonin Pharma Nord 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 Pharma Nord. 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 | Off-label use in paediatric patients with sleep disorders |
| Missing information | Use in individuals with autoimmune disorders<br>Use in patients with renal or hepatic impairment<br>Fertility, pregnancy and lactation |

## *II.B Summary of important risks*

| **Off-label use in paediatric patients with sleep disorders** | |
|---|---|
| Evidence for linking the risk to the medicine | Availability of melatonin products approved for other indications; the European database of suspected adverse drug reaction reports. |
| Risk factors and risk groups | Children and adolescents with any type of sleep disorder |
| Risk minimisation measures | Routine risk minimisation measures:<br>*SmPC section 4.1, 4.2., 4.4. and 5.1*<br>*PL section 1 and 2*<br>*Pack size*<br><br>Additional risk minimisation measures:<br>None |

| **Use in individuals with autoimmune disorders** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>*SmPC section 4.4*<br>*PL section 2* |

| | |
|---|---|
| | Additional risk minimisation measures:<br>None |

| **Use in patients with renal or hepatic impairment** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>*SmPC section 4.2, 4.4 and 5.2*<br>*PL section 2*<br><br>Additional risk minimisation measures:<br>None |

| **Fertility, pregnancy and lactation** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>*SmPC section 4.6 and 5.3*<br>*PL section 2*<br><br>Additional risk minimisation measures:<br>None |

## *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 Pharma Nord.

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

There are no studies required for Melatonin Pharma Nord.