

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

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

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

I. The medicine and what it is used for

Melatonin "Generic Partners" 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 older (see SmPC for the full indication). It contains melatonin as the active substance and it is given orally.

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

Important risks of Melatonin generic partners, together with measures to minimise such risks and the proposed studies for learning more about Melatonin generic partners's risks, are outlined below.

Measures to minimise the risks identified for medicinal product are:

- 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.

If important information that may affect the safe use of Melatonin generic partners is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Melatonin generic partners 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 generic partners. 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).

Summary of safety concerns	
Melatonin generic partners	
Important identified risks	<ul style="list-style-type: none"> Nightmares
Important potential risks	<ul style="list-style-type: none"> Hyperprolactinaemia / Galactorrhoea Sperm motility decreased / Spermatozoa morphology abnormal Suicide attempt / suicidal ideation / mood disturbances / depression / anxiety / depressed mood Psychotic disorders Panic attacks Confusion Hallucinations Drug interaction with levothyroxine Potential interaction with warfarin Loss of consciousness Infections Withdrawal Retinal effects Dyspnoea
Missing information	<ul style="list-style-type: none"> Off label use Use in pregnancy / lactation

II.B Summary of important risks

Not applicable.

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 generic partners.

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

There are no studies required for Melatonin generic partners.