PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Voquily 1 mg/ml oral solution

This is a summary of the risk management plan (RMP) for Voquily 1 mg/ml oral solution. The RMP details important risks of Voquily 1 mg/ml oral solution, how these risks can be minimised, and how more information will be obtained about Voquily 1 mg/ml oral solution's risks and uncertainties (missing information).

Voquily 1 mg/ml oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Voquily 1 mg/ml oral solution should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Voquily 1 mg/ml oral solution is authorised for sleep onset insomnia resulting from disturbances of the normal sleep-wake cycle in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been inadequate, (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 Voquily 1 mg/ml oral solution, together with measures to minimise such risks and the proposed studies for learning more about Voquily 1 mg/ml oral solution'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 Voquily 1 mg/ml oral solution is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Voquily 1 mg/ml oral solution 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 Voquily 1 mg/ml oral solution. 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	• None
Missing information	• None

II.B Summary of important risks

Not applicable. There are no important risks for Voquily 1 mg/ml oral solution. All important, identified and potential risks are well-known and are monitored by routine pharmacovigilance only and no additional risk minimisation measures apply.

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 Voquily 1 mg/ml oral solution.

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

There are no studies required for Voquily 1 mg/ml oral solution.