Summary of risk management plan for SONIREM/ONIRIA (Zolpidem)

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

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

I. The medicine and what it is used for

SONIREM/ONIRIA 10 mg /ml oral drops, solution is authorised for the short-term treatment of insomnia in adults in situations where the insomnia is debilitating or is causing severe distress for the patient.

SONIREM/ONIRIA 5 mg and 10 mg orodispersible tablets is authorised for the short-term treatment of insomnia in adults.

These medicinal products contain zolpidem as the active substance and they are given by oral use.

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

Important risks of SONIREM/ONIRIA, together with measures to minimise such risks and the proposed studies for learning more about SONIREM/ONIRIA'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, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of zolpidem 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 zolpidem. 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.

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

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

Not applicable.

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 SONIREM/ONIRIA.

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

There are no studies required for SONIREM/ONIRIA.