Part VI: Summary of the risk management plan

VI.1 Summary of risk management plan for Ninotira 2-5 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Ninotira 2-5 mg film-coated tablets. The RMP details important risks of melatonin film-coated tablets, how these risks can be minimised, and how more information will be obtained about melatonin film-coated tablets' risks and uncertainties (missing information).

Ninotira film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how melatonin film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP.

I. The medicine and what it is used for

Ninotira 2-5 mg film-coated tablets is indicated for:

- Insomnia in children and adolescents aged 6-17 with ADHD, where sleep hygiene measures have been insufficient
- Short term treatment of jet lag in adults

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

Important risks of Ninotira 2-5 mg film-coated tablets, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products represent routine risk minimisation measures:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- The proposed 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 medicinal product can be bought only from pharmacies.

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 Ninotira 2-5 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Ninotira 2-5 mg film-coated tablets. 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).

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety profile of Ninotira 2-5 mg film-coated tablets can be considered well-known and no product specific safety concerns were identified which are not adequately covered by the proposed SmPC and PL. No specific safety concerns were identified that require additional risk minimisation measures or additional pharmacovigilance activities.

Important identified risks:

None.

Important potential risks:

None

Missing information:
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 **Ninotira 2-5 mg film-coated tablets.**

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

There are no studies required for **Ninotira 2-5 mg film-coated tablets**.