

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Zopiclone Dune, filmcoated tablets, 3.75 mg and 7.5 mg**

This is a summary of the risk management plan (RMP) for Zopiclone Dune, filmcoated tablets, 3.75 mg and 7.5 mg. The RMP details important risks of Zopiclone Dune, how these risks can be minimised, and how more information will be obtained about Zopiclone Dune 's risks and uncertainties (missing information).

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

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

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

Zopiclone Dune 's is authorised for short term treatment of insomnia (see SmPC for the full indication). It contains zopiclone as the active substance and it is given by mouth.

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

Important risks of Zopiclone Dune 's, together with measures to minimise such risks and the proposed studies for learning more about Zopiclone Dune 's'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.

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 Zopiclone Dune 's 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 Zopiclone Dune 's. 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);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"><li>• None</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• None</li></ul>
Missing information	<ul style="list-style-type: none"><li>• None</li></ul>

## **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned to the reference medicinal product.

### **Important identified risk**

### **Important potential risk**

NA

### **Missing information**

NA

## **II.C Post-authorisation development plan**

NA