

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

### **Summary of risk management plan for Perampanel Orion (perampanel)**

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

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

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

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

Perampanel Orion is indicated for:

- partial seizures (fits starting in one specific part of the brain), including those followed by generalised seizures affecting all of the brain, in patients from 4 years of age;
- primary generalised tonic-clonic seizures (major fits affecting most or all of the brain) in patients from 7 years of age when the cause of epilepsy is unknown.

It contains perampanel as the active substance and it is given by mouth as film-coated tablets (see SmPC for the full information).

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

Important risks of Perampanel Orion, together with measures to minimise such risks and the proposed studies for learning more about Perampanel Orion'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*.

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

## II.A List of important risks and missing information

Important risks of Perampanel Orion 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 perampanel. 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	<ul style="list-style-type: none"><li>• Aggression</li><li>• Interaction with levonorgestrel containing contraceptives, and unintended pregnancy exposures</li><li>• Suicidality</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• Hepatic disorders (excluding hepatic disorders induced by SCARs)</li></ul>
Missing information	<ul style="list-style-type: none"><li>• Impact on cognition and growth in the paediatric population</li><li>• Use in human pregnancy and lactation</li></ul>

SCARs = severe cutaneous adverse reactions

## II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

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

## II.C Post-authorisation development plan

There are no studies required for Perampanel Orion.