

# EU Risk Management Plan (lacosamide)

Part VI - sRMP

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

### **Summary of risk management plan for Lacosamide OPKO 100mg film-tablets.**

This is a summary of the risk management plan (RMP) Lacosamide OPKO 100mg film-tablets (hereinafter referred to as Lacosamide OPKO). The RMP details important risks of Lacosamide OPKO and how more information will be obtained about Lacosamide OPKO risks and uncertainties (missing information).

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

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

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

Lacosamide OPKO is authorised for the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy (see SmPC for the full indication). It contains Lacosamide as the active substances and it is given for oral use.

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

Important risks of Lacosamide OPKO, together with measures to minimise such 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 Lacosamide OPKO 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 Lacosamide OPKO. 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>• Cardiac adverse events (AEs) that may be potentially associated with PR interval prolongation or sodium channel modulation</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• None</li></ul>
Missing information	<ul style="list-style-type: none"><li>• Pregnant or lactating women</li><li>• Impact on long-term growth, long-term neurodevelopment, and on puberty in pediatric population</li></ul>

### ***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***

#### **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 Lacosamide OPKO.

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

There are no studies required for Lacosamide OPKO.