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

### **V.1. Routine Risk Minimisation Measures**

Not applicable

### **V.2. Additional Risk Minimisation Measures**

Routine risk minimization activities as described in Part V.1 are sufficient to manage the safety concerns of the medicinal product. Additional risk minimization measures are not considered necessary.

### **V.3 Summary of risk minimisation measures**

Not applicable

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

This is a summary of the risk management plan (RMP) for lacosamide Dr. Reddy's solution for perfusion. The RMP details important risks of lacosamide, how these risks can be minimised, and how more information will be obtained about lacosamide's risks and uncertainties (missing information).

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

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

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

Lacosamide injection of 10 mg/ml solution for infusion is authorised indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.


Lacosamide injection of 10 mg/ml solution for infusion is indicated as adjunctive therapy

- in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.
- in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy.

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

Important risks of lacosamide, together with measures to minimise such risks and the proposed studies for learning more about lacosamide's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

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- 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 public (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 lacosamide is not yet available, it is listed under 'missing information' below

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


Important risks of lacosamide 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. 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 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 puberty in paediatric population</li> </ul>


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

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

<b>Missing information: Pregnant or lactating women</b>	
Additional Pharmacovigilance activities	Additional Pharmacovigilance activities:  Participations in pregnancies registries as European and International Registry of Antiepileptic Drugs (AEDs) in

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<b>Missing information: Pregnant or lactating women</b>	
	Pregnancy (EURAP) and in the North American AED Pregnancy Registry (NAAPR).

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## ***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.

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

Study (study short name, and title)	Summary of objectives	Safety concerns addressed	Status (planned, started)	Due dates (in DD/MM/YYYY)
European and International Registry of Antiepileptic Drugs (AEDs) in Pregnancy (EURAP)	<p>The primary objective is to collect data on the risk of major congenital malformations following maternal intake of lacosamide.</p> <p>Secondary objectives include the evaluation of:</p> <ul style="list-style-type: none"> <li>- Any specific pattern of foetal abnormalities</li> <li>- Dose-Effect relationships</li> <li>- Other risk factors</li> </ul>	Missing information for use during pregnancy and lactation	EURAP registry is planned. The MAH commits to participate to EURAP.	Not applicable