PART VI- Summary of the risk management plan

Summary of risk management plan for Laprysta.

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

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

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

I. The medicine and what it is used for

Laprysta is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy; and as adjunctive therapy: in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy and in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy (see SmPC for the full indication).

It contains lacosamide as the active substance, and it is given by oral administration.

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

Important risks of Laprysta, together with measures to minimise such risks and the proposed studies for learning more about Laprysta 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 the case of Laprysta, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that prompt action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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

II.A List of important risks and missing information

Important risks of Laprysta 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 Laprysta. 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).

Table-Part VI-1 List of important and potential risks and missing information.

Summary of safety concerns	
Important identified risks	• Cardiac AEs that may be potentially associated with PR interval prolongation and sodium channel modulation
Important potential risks	• None
Missing information	• Pregnant or lactating women • Impact on long-term growth, long-term neurodevelopment, and on puberty in pediatric population aged 4 to < 16 years

AE=adverse event

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 required for Laprysta.

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

European and International Registry of Antiepileptic Drugs (AEDs) in Pregnancy (EURAP).

Purpose of the study: Participation in the EURAP (European Register of Antiepileptic Drugs and Pregnancy) registry.The use in pregnant and lactating women is currently missing information, the objective is to collect detailed data on the risk on pregnancies following lacosamide exposure.

Proposed action:

Participation in the EURAP pregnancy registry. The medical representatives who will be in touch with the HCPs should encourage them to register their pregnant patients suffering from epilepsy in the EURAP registry.

For this purpose, the HCPs should use special protocol forms which will be provided to the HCPs if they decide to participate to the registry after different stages of pregnancy, compare Annex 6.