Summary of risk management plan for Pregabalin Prolonged-release tablets (82.5 mg, 165 mg and 330 mg) (Pregabalin)

This is a summary of the risk management plan (RMP) for Pregabalin prolonged-release tablets (82.5 mg, 165 mg and 330 mg). The RMP details important risks of Pregabalin Prolonged-release tablets, how these risks can be minimised, and how more information will be obtained about Pregabalin Prolonged-release tablets' risks and uncertainties (missing information)

Pregabalin Prolonged-release tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pregabalin Prolonged-release tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Pregabalin Prolonged-release tablets' RMP.

I. The medicine and what it is used for

Pregabalin Prolonged-release tablets (82.5 mg, 165 mg and 330 mg) is authorised for neuropathic pain, epilepsy, and generalised anxiety disorder in adults (see SmPC for the full indication). It contains pregabalin as the active substance and it is given by the oral route of administration.

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

Important risks of Pregabalin Prolonged-release tablets, together with measures to minimise such risks and the proposed studies for learning more about Pregabalin Prolonged-release tablets' 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, including PSUR assessment - 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 Pregabalin Prolonged-release tablets 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 of Pregabalin Prolonged-release tablets. 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).

Summary of safety concerns	
Important identified risks	• Dizziness, Somnolence, Loss of Consciousness, Syncope, and Potential for Accidental Injury • Discontinuation Events • Drug interactions (lorazepam, ethanol, and CNS depressants) • Euphoria • Congestive Heart Failure • Vision-related events • Abuse and Drug Dependence[a]
Important potential risks	• Suicidality • Off-label use in paediatric patients
Missing information	None

a. Abuse and Drug Dependence is an identified risk in the EU only.

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 Pregabalin Prolonged-release tablets.

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

There are no studies required for Pregabalin Prolonged-release tablets.