Part VI: Summary of the risk management plan

Summary of risk management plan for Pregabalin, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules

This is a summary of the risk management plan (RMP) for pregabalin, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg, hard capsules (hereinafter referred as pregabalin). The RMP details important risks of pregabalin, how these risks can be minimized, and how more information will be obtained about pregabalin risks and uncertainties (missing information).

Pregabalin' summary of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how pregabalin should be used.

This summary of the RMP for pregabalin should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR). Important new concerns or changes to the current ones will be included in updates of the pregabalin hard capsules' RMP.

I. The medicine and what it is used for

Pregabalin are authorized for:

Epilepsy

Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.

Generalized Anxiety Disorder (GAD)

Pregabalin is indicated for the treatment of GAD in adults.

Neuropathic pain

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

It contains pregabalin as an active substance and is given orally as hard capsules (25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg).

Further information about the evaluation of pregabalin's benefits can be found in pregabalin's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: Pregabalin Sandoz |European Medicines Agency (EMA).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

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

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PLs and SmPCs addressed to patients and healthcare professionals (HCPs);
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 are risks that need special risk management activities to further investigate or minimize 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 pregabalin. 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	Dizziness, somnolence, loss of consciousness, syncope, and potential for accidental injury
	Euphoria
	Discontinuation events
	Drug interactions [lorazepam, ethanol, and Central Nervous system depressants]
	Congestive heart failure (CHF)
	Vision-related events
Important potential risks	Suicidality
	Off-label use in pediatric patients
Missing information	None

II.B Summary of important risks

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

II. Post-authorization development plan

II.C.1 Studies which are conditions of the Marketing authorization

There are no studies which are conditions of the Marketing authorization or specific obligation of pregabalin.

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

There are no studies required for pregabalin.