

# Summary of risk management plan for Pregabalin Sandoz (Pregabalin)

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

Pregabalin hard capsules' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how pregabalin hard capsules should be used.

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

For EMEA/H/C/4010, DE/H/4164/001-008, DE/H/4167/001-008, EMEA/H/C/4070

### *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.

For EMEA/H/C/4010, DE/H/4164/001-008, DE/H/4167/001-008

### *Neuropathic pain*

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

It contains pregabalin as 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 EMA website, under the medicine's [webpage](#)

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

Important risks of pregabalin hard capsules together with measures to minimize such 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 PL and SmPC addressed to patients and 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, including periodic safety update report (PSUR) assessment (if applicable) 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 pregabalin hard capsules is not yet available, it is listed under 'missing information' below.

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

Important risks of pregabalin hard capsules 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 hard capsules. 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	Dizziness, somnolence, loss of consciousness, syncope, and potential for accidental injury
	Discontinuation events
	Drug interactions [lorazepam, ethanol, and central nervous system (CNS) depressants]
	Euphoria
	Congestive heart failure
	Vision-related events
	Abuse and drug dependence <sup>a</sup>
Important potential risks	Suicidality
	Off-label use in pediatric patients
Missing information	Pregnancy and lactating women

a. Abuse and drug dependence is an identified risk in the European union (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-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 for pregabalin hard capsules.

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

There are no studies required for pregabalin hard capsules.