

# Summary of risk management plan for pregabalin by Krka (pregabalin)

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

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

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

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

Pregabalin by Krka is authorised for treatment of neuropathic pain, epilepsy and generalised anxiety disorder (see SmPC for the full indication). It contains pregabalin as the active substance and it is given orally.

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

Important risks of pregabalin by Krka, together with measures to minimise such risks and the proposed studies for learning more about pregabalin by Krka's 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 by Krka 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 pregabalin by Krka. 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>Summary of safety concerns</b>	
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 <sup>a</sup>
Important potential risks	Suicidality
	Off-label use in paediatric patients
Missing information	None

<sup>a</sup>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 by Krka.

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

There are no studies required for pregabalin by Krka.