Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for Pregabalin Zentiva k.s. (Pregabalin)
This is a summary of the risk management plan (RMP) for Pregabalin Zentiva k.s.. The RMP details important risks of Pregabalin Zentiva k.s. and how more information will be obtained about Pregabalin Zentiva k.s.'s risks and uncertainties (missing information).
Pregabalin Zentiva k.s.'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pregabalin Zentiva k.s. should be used.

This summary of the RMP for Pregabalin Zentiva k.s. 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 Pregabalin Zentiva k.s.'s RMP.

I. The medicine and what it is used for

Pregabalin Zentiva k.s. is authorised for the 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 by oral route of administration.

Further information about the evaluation of Pregabalin Zentiva k.s.'s benefits can be found in Pregabalin Zentiva k.s.'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/pregabalin-zentiva-ks.

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

Important risks of Pregabalin Zentiva k.s., together with measures to minimise such risks and the proposed studies for learning more about Pregabalin Zentiva k.s.'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 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 Zentiva k.s. is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Pregabalin Zentiva k.s. 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 Zentiva k.s.. 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 • Vision related events • Discontinuation events • Congestive heart failure • Drug interactions (lorazepam, ethanol and CNS depressants) • Euphoria • Abuse and drug dependence
Important potential risks	• Suicidality • Off-label use in paediatric patients
Missing information	• Pregnant and lactating women

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 Zentiva k.s..

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

There are no studies required for Pregabalin Zentiva k.s..