Part VI: Summary of the risk management plan

Summary of risk management plan for "Gabapentin 100 mg, 300 mg and 400 mg capsule, hard" and "Gabapentin 600 mg and 800 mg film-coated tablets" (here in referred as gabapentin capsule, hard and gabapentin film-coated tablets)

This is a summary of the risk management plan (RMP) for gabapentin 100 mg, 300 mg and 400 mg capsule, hard and gabapentin 600 mg and 800 mg film-coated tablets. The RMP details important risks of gabapentin capsule, hard and gabapentin film-coated tablets, how these risks can be minimized, and how more information will be obtained about gabapentin capsule, hard and gabapentin film-coated tablets' risks and uncertainties (missing information).

Gabapentin capsule, hard and gabapentin film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how gabapentin capsule, hard and gabapentin film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of gabapentin capsule, hard and gabapentin film-coated tablets' RMP.

I. The medicine and what it is used for

Gabapentin capsule, hard and gabapentin film-coated tablets is authorized for:

- Epilepsy

  Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.

  Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.

- Treatment of peripheral neuropathic pain

  Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

It contains gabapentin as the active substance and it is given by oral route of administration as 15 mg, 30 mg, and 60 mg film-coated tablets.

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

Important risks of gabapentin capsule, hard and gabapentin film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about gabapentin capsule, hard and gabapentin film-coated tablets' 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 package leaflet and SmPC addressed to patients and healthcare professionals;
- 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.*

If important information that may affect the safe use of gabapentin capsule, hard and gabapentin film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of gabapentin capsule, hard and gabapentin film-coated tablets are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered or 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 gabapentin capsule, hard and gabapentin film-coated 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);

List of important risks and missing information	
Important identified risks	Abuse and dependence
	Concomitant use with opioids
	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Important potential risks	Suicidality
	Pancreatitis
Missing information	Long term effects on learning, in growth, endocrine function, puberty and childbearing potential in children
	Use during pregnancy and lactation

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 of gabapentin 100 mg, 300 mg and 400 mg capsule, hard and gabapentin 600 mg and 800 mg film-coated tablets.

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

There are no studies required for gabapentin 100 mg, 300 mg and 400 mg capsule, hard and gabapentin 600 mg and 800 mg film-coated tablets.