Part VI: Summary of the risk management plan

Summary of risk management plan for Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 mg and 800 mg film-coated tablets (gabapentin):

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

Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets' proposed SmPCs and their package leaflets give essential information to healthcare professionals and patients on how Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets should be used.

This summary of the RMP for Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets 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 Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets are proposed for authorisation in:

Epilepsy

Gabapentin is indicated in:

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

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

Important risks of Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning

more about Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets' 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 Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg 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 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg 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);

Important Identified Risk	• Abuse and Dependence
Important Potential Risk	• Suicidal ideation and behaviour • Risk of birth defects
Missing information	• Long term effects on learning, intelligence, growth, endocrine function, puberty and childbearing potential in children

II.B Summary of important risks

The safety information for the other important safety concerns in the proposed Product Information is aligned to the reference medicinal product.[1,2,3,4,5]

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 which is a specific obligation of Gabapentin 100 mg, 300 mg, 400 mg hard capsules and Gabapentin 600 and 800 mg film-coated tablets.

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

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