Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Gabapentin Teva, Gabapentin Teva B.V. and Gabapentin Teva Pharma

This is a summary of the risk management plan (RMP) for Gabapentin Teva, Gabapentin Teva B.V. and Gabapentin Teva Pharma (hereinafter referred to as Gabapentin). The RMP details important risks of Gabapentin, how these risks can be minimised, and how more information will be obtained about product's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Gabapentin is authorised 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, and for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults (see SmPC for the full indication). It contains Gabapentin as the active substance and it is taken orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Gabapentin, together with measures to minimise such risks and the proposed studies for learning more about Gabapentin's risks, if any, 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*.

II.A List of Important Risks and Missing Information

Important risks of Gabapentin 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 Gabapentin. 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). There were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

Table 4: Summary of Safety Concerns

Summary of safety concerns	
Important identified risks	• Suicidal ideation and behaviour • Abuse and dependence
Important potential risks	• 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 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 Gabapentin.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Gabapentin.