Part VI: Summary of the risk management plan

Summary of risk management plan for gabapentin, Shaktatin oral solution:

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

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

I. The medicine and what it is used for

Shaktatin is authorised for epilepsy- adjunctive therapy in the treatment of partial seizures with and without secondary generalisation in adults and children aged 6 years and above. Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalisation in adults and adolescents aged 12 years and above. Gabapentin is also indicated for treatment of peripheral neuropathic pain- such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

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

Important risks of Shaktatin, together with measures to minimise such risks and the proposed studies for learning more about Shaktatin's risks, are outlined below.

Measures to minimize the risks identified for medicinal products are:

- 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 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 Shaktatin 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 Shaktatin. 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	• Suicidal ideation and behaviour • Abuse and dependence • Withdrawal symptoms • Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)
Important potential risks	• Risk of birth defects
Missing information	• Long term effects on learning, intelligence, 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-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 Shaktatin.

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

There are no studies required for Shaktatin.