Part VI: Summary of the risk management plan

Summary of risk management plan for Kigabeq, 100 and 500 mg soluble tablets (vigabatrin)

This is a summary of the risk management plan (RMP) for Kigabeq, 100 and 500 mg soluble tablets. The RMP details important risks of Kigabeq, 100 and 500 mg soluble tablets, and how more information will be obtained about Kigabeq, 100 and 500 mg soluble tablets' risks and uncertainties (missing information).

Kigabeq, 100 and 500 mg soluble tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Kigabeq, 100 and 500 mg soluble tablets should be used.

This summary of the RMP for Kigabeq, 100 and 500 mg soluble 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 Kigabeq, 100 and 500 mg soluble tablets' RMP.

I. The medicine and what it is used for

Kigabeq, 100 and 500 mg soluble tablets is authorised for the treatment in monotherapy of infantile spasms (West's syndrome) and the treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy with or without secondary generalization, in case all other appropriate medicinal product combinations have proved inadequate or have not been tolerated (see SmPC for the full indication). It contains vigabatrin as the active substance and it is given by oral or gastric route of administration.

Further information about the evaluation of Kigabeq, 100 and 500 mg soluble tablets' benefits can be found in Kigabeq, 100 and 500 mg soluble tablets' EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

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

Important risks of Kigabeq, 100 and 500 mg soluble tablets, together with measures to minimise such risks and the proposed studies for learning more about Kigabeq, 100 and 500 mg soluble 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.

II.A List of important risks and missing information

Important risks of Kigabeq, 100 and 500 mg soluble tablets 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 Kigabeq, 100 and 500 mg soluble 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);

Brain cytotoxic edema/MRI abnormalities previously classified as important potential risk is to be reclassified as important identified risk.

List of important risks and missing information	
Important identified risks	Visual field defect Suicidality Brain cytotoxic edema/MRI abnormalities
Important potential risks	Interaction with phenytoin
Missing information	None

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 Kigabeq, 100 and 500 mg soluble tablets.

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

There are no studies required for Kigabeq, 100 and 500 mg soluble tablets