Part VI: Summary of the risk management plan

Summary of risk management plan Brivaracetam STADA 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta (Brivaracetam)

This is a summary of the risk management plan (RMP) for Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta. The RMP details important risks of Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta, how these risks can be minimised, and how more information will be obtained about Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta's risks and uncertainties (missing information). Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta should be used.

Important new concerns or changes to the current ones will be included in updates of Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta's RMP.

I. The medicine and what it is used for

Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy. It contains brivaracetam, as the active substances, and it is given by oral route of administration.

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

Important risks of Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta, together with measures to minimise such risks and the proposed studies for learning more about Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta‘s 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 Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta 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 Brivaracetam STADA and Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta. 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);

Summary of safety concerns	
Important identified risks	• Suicidality (class label for anticonvulsant products)
Important potential risks	• None
Missing information	• Data during pregnancy and lactation • Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, cognitive and psychomotor development in pediatric patients

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 Brivaracetam STADA or Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta.

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

There are no studies required for Applicant's Brivaracetam STADA or Brivaracetam STADA Arzneimittel 10 mg, 25 mg, 50 mg, 75 mg, 100 mg filmtabletta.