Part VI: Summary of the risk management plan

Summary of risk management plan for Gablofen

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

Gablofen's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Gablofen should be used. Important new concerns or changes to the current ones will be included in updates of Gablofen's RMP.

I. The medicine and what it is used for

Gablofen is indicated for

Adults

Gablofen is indicated in patients with severe chronic spasticity resulting from trauma, multiple sclerosis or other spinal cord disorders, who are unresponsive to oral baclofen or other orally administered anti-spastic medicinal products and/or those patients who experience unacceptable side effects at effective oral doses. Gablofen is effective in patients with severe chronic spasticity of cerebral origin, resulting e.g. from cerebral palsy, brain trauma or cerebrovascular accident.

Paediatric population

Gablofen is indicated in patients aged 4 to <18 years with severe chronic spasticity of spinal or cerebral origin (associated with injury, multiple sclerosis, or other spinal cord diseases) who are unresponsive to orally administered anti-spastics (including oral baclofen) and/or who experience unacceptable undesirable effects at effective oral doses.

It contains Baclofen as the active substance and it is given by Intrathecal bolus injection and Continuous intrathecal infusion solution for intrathecal injection/infusion.

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

Important risks of Gablofen, together with measures to minimise such risks and the proposed studies for learning more about Gablofen'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, 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

All the safety concerns for Gablofen have been removed based on the HaRP assessment report (Dated: 20-May-2021). Therefore, routine risk minimization measures and additional risk minimization measures is excluded.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
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 Gablofen.

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

There are no studies required for Gablofen