Part VI: Summary of the risk management plan

Summary of risk management plan for Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion

This is a summary of the risk management plan (RMP) for Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion. The RMP details important risks of Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion, how these risks can be minimised, and how more information will be obtained about Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion's risks and uncertainties (missing information).

Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion should be used.

I. The medicine and what it is used for

Baclofen Accord is indicated in patients with severe chronic spasticity of spinal or cerebral origin (associated with injury, multiple sclerosis, cerebral palsy) who are unresponsive to oral baclofen or other orally administered antispastic agents and/or those patients who experience unacceptable side-effects at effective oral doses.

In patients with spasticity due to head injury a delay of at least one year before treatment with Baclofen Accord Intrathecal is recommended, to allow the symptoms of spasticity to stabilise. Baclofen Accord Intrathecal may be considered as an alternative to ablative neurosurgical procedures.

Paediatric population

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

It contains baclofen as the active substance and it is given by intrathecal route.

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

Important risks of Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion'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

Important risks of Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion 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 Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion. 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);

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 Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion.

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

There are no studies required for Baclofen Accord 50 mcg/ml solution for injection and 0.5 mg/ml and 2 mg/ml solution for infusion.