Part VI: Summary of the risk management plan

Summary of risk management plan for Baclofen Xiromed (Baclofen)

This is a summary of the risk management plan (RMP) for Baclofen Xiromed. The RMP details important risks of Baclofen Xiromed and how more information will be obtained about Baclofen Xiromed risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Baclofen Xiromed RMP.

I. The medicine and what it is used for

Baclofen Xiromed is authorised for muscular spasms of spinal or cerebral origin (see SmPC for the full indication). It contains baclofen as the active substance and given as a tablet.

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

Important risks of Baclofen Xiromed, together with measures to minimise such risks and the proposed studies for learning more about Baclofen Xiromed 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 Baclofen Xiromed tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Baclofen Xiromed are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Xiromed. 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	1. Withdrawal symptoms 2. Overdose/lack of efficacy
Important potential risks	None
Missing information	3. Use in pregnant or breast feeding women

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

Not applicable.

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

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

There are no studies required for Baclofen Xiromed.