Part VI: Summary of the risk management plan

Summary of risk management plan for Crisantaspase Porton Biopharma (Crisantaspase (L-asparaginase from *Erwinia chrysanthemi*))

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

Crisantaspase Porton Biopharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Crisantaspase Porton Biopharma should be used.

I. The medicine and what it is used for

Crisantaspase Porton Biopharma is authorised as part of a treatment regimen for the treatment of patients with acute lymphoblastic leukaemia (see SmPC for the full indication). It contains Crisantaspase as the active substance and it is given by injection or infusion into the vein or injection into the muscle.

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

Important risks of Crisantaspase Porton Biopharma, together with measures to minimise such risks and the proposed studies for learning more about Crisantaspase Porton Biopharma'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*.

II.A List of important risks and missing information

Important risks of Crisantaspase Porton Biopharma 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 Crisantaspase Porton Biopharma. 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).

Table II.1: Lists of Important Risks and Missing Information

Summary of Safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.C Post-authorisation development plan

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

There are no studies which are either conditions of the marketing authorisation or specific obligations for Crisantaspase Porton Biopharma.

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

Not Applicable