PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Abcur AB. Thiotepa Abcur 15 mg and 100 mg powder for concentrate for solution for infusion; herein after referred to as Thiotepa.

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

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

Important new concerns or changes to the current ones will be included in updates of Thiotepa's RMP.

I. The medicine and what it is used for

Thiotepa contains the active substance thiotepa, which belongs to a group of medicines called alkylating agents. Thiotepa is used to prepare patients for bone marrow transplantation. It works by destroying bone marrow cells. This enables the transplantation of new bone marrow cells (haematopoietic progenitor cells), which in turn enable the body to produce healthy blood cells. Thiotepa can be used in adults, children and adolescents.

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

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

If important information that may affect the safe use of Thiotepa is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Thiotepa 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 Thiotepa. 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).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Important identified risk

None

Important Potential risk

None

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 for Thiotepa Abcur 15 mg and 100 mg powder for concentrate for solution for infusion.

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

There are no studies required for Thiotepa Abcur 15 mg and 100 mg powder for concentrate for solution for infusion.