Part VI: Summary of the risk management plan

Summary of risk management plan for Thiotepa medac powder for concentrate for solution for infusion

This is a summary of the risk management plan (RMP) for Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion. The RMP details important risks of Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion' risks and uncertainties (missing information).

Thiotepa medac's 15 mg and 100 mg powder for concentrate for solution for infusion' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion's RMP.

I. The medicine and what it is used for

Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion 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 medac can be used in adults and children and adolescents.

It is indicated, in combination with other chemotherapy medicinal products:

- with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;
- when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.

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

Important risks of Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion' 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 Thiotepa medac 15 mg and 100 mg powder for concentrate for solution for infusion is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of Thiotepa medac 15 mg and 100 mg powder for concentrate for 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 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 medac 15 mg and 100 mg powder for concentrate for 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).

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

Not applicable.

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

Not applicable.