# PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

**Summary of risk management plan for Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion (Amphotericin B liposomal):**

This is a summary of the risk management plan (RMP) for Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion. The RMP details important risks of Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion, how these risks can be minimised, and how more information will be obtained about Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion's risks and uncertainties (missing information).

Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion's RMP.

## I. The medicine and what it is used for

Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion is authorised in adults and paediatric patients aged 1 month and older for

- the treatment of severe systemic or deep mycoses
- Empirical treatment of suspected fungal infections in febrile neutropenic patients.

Until sufficient study data are available, Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion can be used as a secondary therapy for visceral leishmaniasis (*Leishmania donovani*) in immunocompetent patients and in patients with compromised immune systems (e.g. people living with HIV). (See SmPC for the full indication)

It contains Amphotericin B liposomal as the active substance and it is given by intravenous infusion.

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

Important risks of Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion, together with measures to minimise such risks and the proposed studies for learning more about Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion 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 health care 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 Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion 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 Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion 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***

There are no studies which are conditions of the marketing authorisation or specific obligation of Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion.

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

There are no studies required for Amphotericin B liposomal Tillomed 50 mg Powder for concentrate for dispersion for infusion.