Summary of risk management plan for Foscarnet Tillomed 24 mg/ml solution for infusion

This is a summary of the risk management plan (RMP) for Foscarnet Tillomed 24 mg/ml solution for infusion. The RMP details important risks of Foscarnet Tillomed 24 mg/ml solution for infusion, how these risks can be minimised and how more information will be obtained about Foscarnet Tillomed 24 mg/ml solution for infusion's risks and uncertainties (missing information).

Foscarnet Tillomed 24 mg/ml solution for infusion's Summary of Product Characteristic (SPC) and Patient Information Leaflet (PIL) gives essential information to healthcare professionals and patients on how foscarnet should be used.

I. The medicine and what it is used for

Foscarnet Tillomed 24 mg/ml solution for infusion should be used in patients with acquired immune deficiency syndrome (AIDS) with the following conditions only:

- Induction and maintenance treatment in CMV retinitis (cytomegalovirus) in patients with HIV infection. Cytomegalovirus (CMV) induced life-threatening illness or illnesses threatening the vision. Foscarnet should be used provided cytomegalovirus has been detected by means of discharge laboratory tests, sensitivity and specificity.
- For acute, mucocutaneous infections caused by aciclovir-resistant herpes simplex viruses (HSV). Foscarnet therapy should be given if there are no medically acceptable therapeutic alternatives. Due to the risk profile of the active ingredient, a strict indication is required. If there is a relapse, the aciclovir resistance must be reviewed. The diagnosis of the lack of response to aciclovir can be established clinically by checking the lack of response to an intravenous aciclovir treatment (5-10 mg / kg tid) for 10 days or by assay in vitro. The safety and efficacy of foscarnet sodium in the treatment of other HSV infections (e.g., retinitis, encephalitis), congenital or neonatal disease or HSV in immunocompetent individuals have not been established.
- Induction treatment of CMV infections associated with Human immunodeficiency virus (HIV) of the upper and lower gastrointestinal tract, pulmonary and encephalic.

Foscarnet Tillomed 24 mg/ml solution for infusion is also indicated in patients who have undergone hematopoietic stem cell transplantation (HSCT), when first-line treatment is not considered adequate and for which the use of ganciclovir cannot be considered:

- In the early treatment of CMV viremia in high-risk patients
- In the treatment of CMV infection

Foscarnet Tillomed 24 mg/ml solution for infusion is not recommended for treatment of CMV infections other than retinitis or HSV or for use in non-AIDS or non-immunocompromised patients.

It contains Foscarnet as the active substance and it is given by intravenous route.

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

Important risks of Foscarnet Tillomed 24 mg/ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Foscarnet Tillomed 24 mg/ml solution 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 SPC/PIL 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 as 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 Foscarnet Tillomed 24 mg/ml 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 taken. 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 Foscarnet Tillomed 24 mg/ml 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

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

There are no studies required for Foscarnet Tillomed 24 mg/ml solution for infusion.