PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

This is a summary of the risk management plan (RMP) for Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion. The RMP details important risk of Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion, how these risks can be minimized and how more information will be obtained about Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion risk and uncertainties (missing information).

Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion is authorised for the treatment of CMV retinitis in adults with acquired immunodeficiency syndrome (AIDS) and without renal dysfunction. It should be used only when other medicinal products are considered unsuitable. It contains Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion as the active substance and it is given by concentrate for solution for infusion.

II. Risk associated with the medicine and activities to minimize or further characterize the risk

Important risks of Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion, together with measures to minimize such risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be

- Specific information, such as warning, precautions and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professional.
- Important advice on the medicines packaging
- The authorized pack size- the amount of medicine in the pack is chosen so to ensure that the medicine is used correctly
- The medicines legal status- the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse events is collected continuously and regular analysed, including PSUR assessment, 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 Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion is not yet available, it is listed under missing information.

II. A. List of Important risks and missing information

Important risks of Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safety administered to patients. 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 Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion. Potential risk are concerns for which as association with the use of this medicine is possible based on available data, but this association has not been established yet and need 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/use in special patient population etc.)

Table 3. Part VI. Summary of safety concerns

Summary of safety concerns	
Important identified risk	• 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- authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion.

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

There are no studies required for Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion.