

PART VI: Summary of the risk management plan

Summary of risk management plan for Foscarnet CampusPharma

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

Foscarnet CampusPharma's Product Information gives essential information to healthcare professionals and patients on how foscarnet should be used.

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

I. The medicine and what it is used for

Foscarnet CampusPharma is indicated for the treatment of cytomegalovirus (CMV) retinitis, CMV viraemia, CMV disease, CMV infection in the gastrointestinal tract and mucocutaneous herpes simplex viral infection (see Product Information for the full indication). It contains foscarnet as the active substance and it is given by intravenous route of administration.

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

Important risks of Foscarnet CampusPharma, together with measures to minimise such risks for learning more about Foscarnet'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.

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 Foscarnet CampusPharma 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 foscarnet. 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

Not applicable

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 Foscarnet CampusPharma.

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

There are no studies required for Foscarnet CampusPharma.