Summary of risk management plan for Aciclovir 250 mg, 500 mg Powder for solution for infusion (acyclovir)

This is a summary of the risk management plan (RMP) for Aciclovir 250 mg, 500 mg Powder for solution for infusion (hereinafter referred to as ACICLOVIR). The RMP details important risks of ACICLOVIR, how these risks can be minimised, and how more information will be obtained about ACICLOVIR risks and uncertainties (missing information).

ACICLOVIR's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ACICLOVIR should be used.

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

I. The medicine and what it is used for

ACICLOVIR is indicated in immunosuppressed patients for:

Infections with the Varicella zoster (VZV) virus

Infection with the Herpes simplex (HSV) virus

ACICLOVIR is indicated in immunocompetent patients for:

VZV infections

- Severe shingles due to the extent of lesions or their capacity for progression
- Chickenpox in pregnant women where the rash occurs 8-10 days before delivery.
- Varicella in neonates
- Neonates before any rash, when the onset of chickenpox occurred in the mother within 5 days before and 2 days after childbirth
- Severe forms of chickenpox in children under 1 year of age
- Complicated chickenpox, especially varicella pneumonia

HSV infections

- Severe primary genital herpes infection
- Treatment of acute herpetic gingivostomatitis, when functional discomfort makes oral treatment impossible
- Kaposi-Juliusberg dermatitis (eczema herpeticum)
- Treatment of herpetic meningoencephalitis

(See SmPC for the full indication).

It contains aciclovir as the active substance and it is administered intravenously.

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

Important risks of ACICLOVIR, together with measures to minimise such risks and the proposed studies for learning more about ACICLOVIR'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 analyzed 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 ACICLOVIR 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 ACICLOVIR. 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 longterm 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 ACICLOVIR.

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

There are no studies required for ACICLOVIR.