Part VI: Summary of the risk management plan

Summary of risk management plan for Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten (Aciclovir)

This is a summary of the risk management plan (RMP) for Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten. The RMP details important risks of Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten, how these risks can be minimised, and how more information will be obtained about Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten's risks and uncertainties (missing information).

Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten should be used.

Important new concerns or changes to the current ones will be included in updates of Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten's RMP.

I. The medicine and what it is used for

Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion is indicated for:

- The treatment of Herpes simplex infections in immunocompromised patients and severe initial genital herpes in the non-immunocompromised.
- The prophylaxis of Herpes simplex infections in immunocompromised patients.
- The treatment of Varicella zoster infections.
- The treatment of herpes encephalitis.
- The treatment of Herpes simplex infections in the neonate and infant up to 3 months of age.

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

Aciclovir Accord 200, 400, 800 mg tablets are indicated for following indications:

- Aciclovir oral formulations are used for the treatment of infections of the skin and mucous membranes caused by the herpes simplex virus, including primary and recurrent genital herpes (apart from herpes simplex virus infections in neonates and severe herpes simplex virus infections in immunocompromised children).
- Aciclovir oral formulations are used for the suppression of recurrent infections (recurrence prevention) caused by the herpes simplex virus in immunocompetent patients.
- Aciclovir oral formulations are used for the prevention of infections caused by the herpes simplex virus in immunocompromised patients.
- Aciclovir oral formulations are used for the treatment of infections caused by the varicella zoster virus (chickenpox) and the herpes zoster virus (shingles). Studies have shown that early treatment of shingles with aciclovir has a positive effect on pain and can reduce the incidence of post-herpetic neuralgia.
- Aciclovir is indicated for the treatment of severely immunocompromised patients, in particular with advanced HIV (CD4+ below 200/mm^3, including patients with AIDS or severe ARC) or following bone marrow transplant. Clinical studies have shown that oral Aciclovir Accord administered in combination with another anti-viral therapy (mainly oral Retrovir) lowered mortality in patients with advanced-stage HIV. Mortality in patients following bone marrow transplant is reduced if preceded by one month's treatment with aciclovir.
- Aciclovir oral formulations also provide effective prevention for herpes virus diseases.

It contains aciclovir as the active substance and it is given by oral route.

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

Important risks of Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten together with measures to minimise such risks and the proposed studies for learning more about Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten 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 Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten 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 Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten. 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).

Important identified risk (s)	• None
Important potential risk (s)	• 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 Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten.

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

There are no studies required for Aciclovir Accord 25 mg/ml Concentrate for Solution for Infusion and Aciclovir Accord 200, 400 and 800 mg, tabletten.