VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Aciclovir is an antiviral drug, that is active against herpes viruses, including herpes simplex 1 and 2 (cold sores and genital herpes), varicella-zoster (chickenpox), and Epstein-Barr virus (mononucleosis). Viruses take over living cells and reproduce themselves, often at the expense of the host cell.

About 80% of the Danish population is infected with HSV-1 and 20% with HSV-2. Infection occurs through spread of the virus to mucous membranes and less frequently on the skin. The source of infection is an infected person in excreted virus in oral or genital secretions.

VI.2.2 Summary of treatment benefits

Aciclovir slows the growth and spread of the herpes virus so that the body can fight off the infection. Aciclovir will not cure herpes, but it can lessen the symptoms of the infection.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Risk	What is known	Preventability
Allergy (hypersensitivity)	Aciclovir or any of the excipients in the tablets can cause hypersensitivity in susceptible patients.	Warning about the condition is given to doctors in the SPC section 4.3 Contraindications and 4.8 Undesirable effects and in to the patients in the PIL section 2.
Renal impairment	Aciclovir is excreted unchanged by the kidney and high doses may cause nephrotoxicity unless adequate hydration is maintained. The risk of renal impairment is increased when other nephrotoxic drugs are used concomitantly.	Patients with renal impairment or severely decreased kidney function should be treated with aciclovir only after considering this condition and dose adjustment as applicable. Warning about the condition is given to doctors in the SPC section 4.2 Dosing and in section 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Decreased virus sensitivity with prolonged or repeated courses of acyclovir in severely immune-compromised patients	Prolonged or repeated courses of acyclovir in severely immune compromised patients may result in the presence of virus that is less susceptible to aciclovir. The resultant risk is that the patient does not respond to further treatment with aciclovir.	Warning about the condition is given to doctors in the SPC section 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Use in lactating women	Aciclovir is excreted in breast milk and high doses of drug to the mothercan result in transfer of significant doses of acyclovir to nursing infants.	Warning about the condition is given to doctors in the SPC section 4.6 Pregnancy and lactation and in to the patients in the PIL section 2.
Neurological side effects (elderly and renally impaired)	Patients that elderly patients and patients with impaired renal function may be at risk for neurological side effects.	Warning about the condition is given to doctors in the SPC section 4.4 Special warnings and precautions for use and in

Risk	What is known	Preventability
		to the patients in the PIL section 2.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Aciclovir Alternova can be found on the homepage of the Danish Health and Medicines Agency after the product has been approved.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not Applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not Applicable.