LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Ganciclovir Oresund Pharma (ganciclovir sodium)

# SE/H/2213/01/DC

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# Summary Public Assessment Report

Ganciclovir Oresund Pharma
ganciclovir sodium

Powder for concentrate for solution for infusion, 500 mg

This is a summary of the public assessment report (PAR) for Ganciclovir Oresund Pharma. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Ganciclovir Oresund Pharma and what is it used for?**
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymevene.

**How does Ganciclovir Oresund Pharma work?**

Ganciclovir Oresund Pharma is used to treat diseases caused by a virus called cytomegalovirus (CMV) in adults and adolescent patients 12 years and older who have a weak immune system. It is also used to prevent CMV infection after an organ transplant or during chemotherapy in adults and children from birth.

**How is Ganciclovir Oresund Pharma used?**

The pharmaceutical form is powder for concentrate for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

**What benefits of Ganciclovir Oresund Pharma have been shown in studies?**

No additional studies were needed as the product is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Cymevene.

**What are the possible side effects from Ganciclovir Oresund Pharma?**
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

**Why is Ganciclovir Oresund Pharma approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Cymevene, the benefits are greater than its risks and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Ganciclovir Oresund Pharma?**

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Ganciclovir Oresund Pharma**

The full PAR for Ganciclovir Oresund Pharma can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Ganciclovir Oresund Pharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-01.