LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Virafosc
(foscarnet sodium hexahydrate)

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foscarnet sodium hexahydrate

Solution for infusion, 24 mg/ml

This is a summary of the public assessment report (PAR) for Virafosc. 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 Virafosc 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 Foscavir 24 mg/ml solution for infusion.

Virafosc is used in adults to treat the following infections that are caused by a virus called cytomegalovirus (CMV):

- An eye infection caused by a virus in people with AIDS. The infection is known as CMV retinitis.
- CMV infections of the organs in the gastrointestinal tract in people with AIDS.
- CMV viraemia or disease. Virafosc is given to people with CMV infection after having a bone marrow transplant. A bone marrow transplant is also known medically as a haematopoietic stem cell transplant (HSCT). The infection can cause disease in any organ and can sometimes be detected before the patient starts to suffer signs of illness. This is called CMV viraemia.

Virafosc is also used to treat the infections caused by a virus called Herpes Simplex Virus (HSV). It is given to people with HSV who have a weakened immune system and have not got better from HSV after having a medicine called aciclovir.

How does Virafosc work?

Virafosc contains the active substance foscarnet. It belongs to a class of medicines called antivirals and it works by stopping viruses from multiplying in number.

How is Virafosc used?

The pharmaceutical form is Solution for infusion (for intravenous use).

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 Virafosc 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, Foscavir 24 mg/ml solution for infusion.

What are the possible side effects from Virafosc?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Virafosc approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and efficacy, and is similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Foscavir 24 mg/ml solution for infusion, 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 Virafosc?

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 Virafosc

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

This summary was last updated in 2023-02.