LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sitavig
(aciclovir)

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Summary Public Assessment Report

Sitavig
(aciclovir)

Muco-adhesive buccal tablets, 50 mg

This is a summary of the public assessment report (PAR) for Sitavig. It explains how Sitavig was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Sitavig.

For practical information about using Sitavig, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sitavig and what is it used for?

Sitavig is used for the treatment of recurrent cold sores on the lips, caused by herpes simplex virus.

How does Sitavig work?

Sitavig inhibits the virus ability to reproduce and therefore make the infection to reverse.

How is Sitavig used?

The pharmaceutical form of Sitavig is muco-adhesive buccal tablets for oral 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.

What benefits of Sitavig have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Sitavig is effective in treating recurrent cold sores on the lips, caused by herpes simplex virus.

What are the possible side effects of Sitavig?

For the full list of all side effects reported with Sitavig, see section 4 of the package leaflet.

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

Why is Sitavig approved?

It was noted that the effect of Sitavig in the treatment of recurrent cold sores on the lips, caused by herpes simplex virus, was significantly better than treatment with placebo.

Therefore, the Medical Products Agency in Sweden decided that Sitavig's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Sitavig?

A risk management plan has been developed to ensure that Sitavig 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 for Sitavig, 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 Sitavig

The marketing authorisation for Sitavig was granted on 2013-02-21 in Sweden.

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

This summary was last updated in 2015-01.