

Summary Public Assessment Report

Zoviduo (acyclovir and hydrocortisone)

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(acyclovir and hydrocortisone)

Cream, 50 mg/g aciclovir and 10 mg/g hydrocortisone

This is a summary of the public assessment report (PAR) for Zoviduo. It explains how Zoviduo 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 Zoviduo.

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

What is Zoviduo and what is it used for?

Zoviduo cream is used for the treatment of early signs and symptoms (e.g. tingling, itching or redness) of cold sores on the lips and face to reduce the chance of a cold sore progressing to a blister .

Zoviduo can be used by adults and adolescents aged 12 years and older.

How does Zoviduo work?

A cold sore is caused by a virus called herpes simplex. The virus causes blisters and sores primarily on the lips but sometimes also in other areas on the face. A cold sore can develop when the body's immune system is weakened, for example when you have a cold or other infection. Stress, strong sunlight, cold temperatures or menstruation can also trigger a cold sore.

Zoviduo contains two active substances: aciclovir and hydrocortisone. Aciclovir is an antiviral that helps to fight the virus that causes cold sores. Hydrocortisone is a mild steroid that reduces the inflammation associated with a cold sore.

How is Zoviduo used?

The pharmaceutical form of Zoviduo is cream for cutaneous use only.

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 be obtained without a prescription.

What benefits of Zoviduo have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Zoviduo is effective in treating early signs and symptoms of recurrent herpes labialis (cold sores) to reduce the progression of cold sore episodes to ulcerative lesions in immunocompetent adults and adolescents (12 years of age and older).

What are the possible side effects of Zoviduo?

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

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

Why is Zoviduo approved?

It was noted that the effect of Zoviduo in the treatment of early signs and symptoms of recurrent herpes labialis (cold sores) to reduce the progression of cold sore episodes to ulcerative lesions in immunocompetent adults and adolescents (12 years of age and older) was significantly better than treatment with placebo. Therefore, the Medical Products Agency in Sweden decided that Zoviduo'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 Zoviduo?

A risk management plan has been developed to ensure that Zoviduo 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 Zoviduo, 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 Zoviduo

The marketing authorisation for Zoviduo was granted on 2009-11-20 in Sweden.

The full PAR for Zoviduo can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Zoviduo, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-03.