LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vectatone
(penciclovir)

SE/H/1410/01/MR

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(penciclovir)

cream, 1 %

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

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

What is Vectatone and what is it used for?

Vectatone is a beige to light brown cream that is used for the treatment of cold sores (herpes labialis) caused by herpes simplex.

How does Vectatone work?

Vectatone inhibits the ability of the herpes simplex virus to multiply. The time needed for healing and the duration of pain and visible signs of the virus are shortened by up to 24 hours. The cream should be applied as soon as possible when symptoms appear.

How is Vectatone used?

The pharmaceutical form of Vectatone is cream for external cutaneous use.

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

A prescription might be needed for this medicine.

What benefits of Vectatone have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Vectatone is effective in treating cold sores (herpes labialis) caused by herpes simplex.

What are the possible side effects of Vectatone?

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

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

Why is Vectatone approved?

It was noted that the effect of Vectatone in the treatment of cold sores (herpes labialis) caused by herpes simplex, was significantly better than treatment with placebo. Therefore, the Medical Products Agency in Sweden decided that Vectatone'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 Vectatone?

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

The marketing authorisation for Vectatone was granted on 2013-06-13 in Sweden.

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

This summary was last updated in 2015-01.