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EPAR summary for the public

Oxervate

cenegermin

This is a summary of the European public assessment report (EPAR) for Oxervate. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Oxervate.

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

What is Oxervate and what is it used for?

Oxervate is a medicine used to treat neurotrophic keratitis, an eye condition in which damage to the trigeminal nerve supplying the surface of the eye causes loss of sensation and defects that do not heal naturally.

The medicine is only used in adults with moderate or severe disease.

Because the number of patients with neurotrophic keratitis is low, the disease is considered 'rare', and Oxervate was designated an 'orphan medicine' (a medicine used in rare diseases) on 14 December 2015.

Oxervate contains the active substance cenegermin.

How is Oxervate used?

Oxervate is available as eye drops. The recommended dose is 1 drop in the affected eye every 2 hours, 6 times per day. Treatment should continue for 8 weeks.

Oxervate can only be obtained with a prescription and treatment should be started and supervised by an eye specialist.

For further information, see the package leaflet.

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How does Oxervate work?

Patients with neurotrophic keratitis have lower than normal levels of substances including growth factors that are normally supplied by the trigeminal nerve and which play an important role in the growth and survival of the cells of the eye's surface. The active substance in Oxervate, cenegermin, is a copy of a human growth factor called nerve growth factor. When given as eye drops to patients with neurotrophic keratitis, cenegermin helps restore some of the normal healing processes in the eye and repair damage to the eye's surface associated with the condition.

What benefits of Oxervate have been shown in studies?

Oxervate has been shown to help heal damage to the eye's surface in 2 main studies involving a total of 204 adults with moderate or severe neurotrophic keratitis. In the first study, 74% (37 out of 50) of patients treated with Oxervate for 8 weeks achieved complete healing of the eye's surface compared with 43% (22 out of 51) of patients treated with a dummy treatment containing the same eye drop formula but no active substance. In the second study, figures were 70% (16 out of 23) with Oxervate and 29% (7 out of 24) with the dummy treatment.

What are the risks associated with Oxervate?

The most common side effects with Oxervate (which may affect more than 1 in 100 people) are eye pain and inflammation, increased lacrimation (watery eyes), pain in the eyelid and sensation of a foreign body in the eye.

For the full list of all side effects and restrictions with Oxervate, see the package leaflet.

Why is Oxervate approved?

Oxervate has been shown to increase by around 30-40% the number of patients who achieve complete healing of the eye's surface when compared with eye drops containing no active substance. Side effects with Oxervate are mainly related to the eye, are mild or moderate in severity and resolve over time.

The European Medicines Agency therefore decided that Oxervate's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Oxervate have been included in the summary of product characteristics and the package leaflet.

Other information about Oxervate

The European Commission granted a marketing authorisation valid throughout the European Union for Oxervate on 06 July 2017.

The full EPAR for Oxervate can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Oxervate, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Oxervate can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 07-2017.