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EPAR summary for the public

Ikervis

ciclosporin

This is a summary of the European public assessment report (EPAR) for Ikervis. 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 Ikervis.

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

What is Ikervis and what is it used for?

Ikervis is a medicine used to treat severe keratitis, an inflammation of the cornea (the transparent layer covering the front of the eye) in adult patients with dry eye disease. It is used when treatment with artificial tears (tear substitutes) is insufficient to improve the condition.

Ikervis contains the active substance ciclosporin.

How is Ikervis used?

Ikervis can only be obtained with a prescription and treatment should only be started by a healthcare professional trained in ophthalmology (eye medicine).

The medicine is available as single-dose eye drops and the recommended dose is one drop in each affected eye daily at bedtime. The doctor should confirm the need for continuing treatment at least every 6 months. If other eye drops are used, the different medicines must be given at least 15 minutes apart. Ikervis should be given last.

For further information, see the package leaflet.

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How does Ikervis work?

In patients with dry eye disease, either not enough tear fluid is produced to create the protective film of moisture that normally coats the surface of the eye, or abnormalities in the tear fluid cause it to dry out too quickly. Without sufficient protection from the tear fluid, the cornea can get damaged and become inflamed (keratitis), which can eventually lead to ulceration, infection and reduced vision.

The active substance in Ikervis, ciclosporin, acts on cells of the immune system (the body's natural defences) that are involved in the processes that cause inflammation. Applying it directly to the eye reduces inflammation and damage there but limits its effects elsewhere in the body.

What benefits of Ikervis have been shown in studies?

The benefits of Ikervis have been shown in one main study involving 246 patients with severe dry eye disease, where Ikervis was compared with the vehicle (the same eye drop formula but without any active substance). The main measure of effectiveness was the proportion of patients whose condition responded to treatment after six months, as measured by a combination of damage to the cornea and a score for the level of symptoms, including discomfort and pain. About 29% (44 of 154) of those given Ikervis responded, compared with 23% (21 of 91) given the vehicle. The proportion of patients who responded to treatment was therefore similar in the two groups, but when only the damage to the cornea was considered, Ikervis was significantly better than the vehicle at reducing it. Levels of HLA-DR (a measure of inflammation in eye cells) were also reduced in patients using Ikervis compared with the dummy treatment.

What are the risks associated with Ikervis?

The most common side effects with Ikervis (which may affect more than 1 in 10 people) are pain and irritation in the eye; other common side effects are lacrimation (excessive tears), ocular hyperaemia (red eye), and erythema (redness) of the eyelid. These symptoms are usually short lasting and occur at the time the eye drops are used. For the full list of all side effects reported with Ikervis, see the package leaflet.

The medicine must not be used in patients who have or are suspected to have an infection of the eye or the tissues around the eye. For the full list of restrictions, see the package leaflet.

Why is Ikervis approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ikervis's benefits are greater than its risks and recommended that it be approved for use in the EU. Although Ikervis had not been shown to be any better than the vehicle in improving symptoms such as discomfort and pain, there was evidence that it could reduce the inflammation and damage to the cornea associated with keratitis. The CHMP considered that this was clinically meaningful, since none of the available medicines for the condition have been shown to reduce damage to the surface of the eye, which might help prevent the progression of the disease. Regarding safety, the medicine was well tolerated, with mainly short-lasting effects on the eye at the time the eye drops are used; the risk of effects on the body as a whole was considered to be low.

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

A risk management plan has been developed to ensure that Ikervis 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 Ikervis, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Ikervis

The European Commission granted a marketing authorisation valid throughout the European Union for Ikervis on 19 March 2015.

The full EPAR and risk management plan summary for Ikervis 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 Ikervis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.