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Vevizye (*ciclosporin*)

An overview of Vevizye and why it is authorised in the EU

What is Vevizye and what is it used for?

Vevizye is a medicine for adults with moderate to severe dry eye disease (also known as keratoconjunctivitis sicca) which has not improved despite treatment with tear substitutes.

Vevizye contains the active substance ciclosporin.

How is Vevizye used?

Vevizye can only be obtained with a prescription. Treatment should be started and supervised by an ophthalmologist (eye specialist).

Vevizye is available as eye drops, with one drop applied to each eye twice daily.

For more information about using Vevizye, see the package leaflet or contact your doctor or pharmacist.

How does Vevizye 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 (the transparent layer in front of the eye that covers the pupil and iris) can get damaged and become inflamed, which can eventually lead to ulceration (formation of open sores), infection and reduced vision.

The active substance in Vevizye, ciclosporin, reduces the activity of cells of the immune system (the body's natural defences) that are involved in inflammation. Applying Vevizye to the eye is expected to reduce inflammation of the cornea and improve symptoms of the disease.

What benefits of Vevizye have been shown in studies?

Two main studies, involving over 1,100 adults with moderate to severe dry eye disease which had not improved despite treatment with tear substitutes, have shown that Vevizye was effective at reducing signs of dry eye disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The studies, which compared the effects of Vevizye with those of a vehicle (the same eye drop formula but without any active substance), looked at the reduction in total corneal fluorescein staining (tCFS) score, which measures corneal damage on a scale ranging from 0 (no damage) to 15 (severe damage); at the start of the study, people had a tCFS score of at least 10.

In the first study, after 29 days of treatment, the tCFS score was reduced by 2.9 in patients treated with Vevizye compared with 2.2 for those who received the vehicle. In the second study, reductions were 4.3 for people given Vevizye and 3.9 for people given vehicle.

The first study also looked at the effects of Vevizye on vision and dry eye symptoms, including discomfort and pain, using the ocular surface disease index (OSDI). This index is based on responses to a questionnaire and ranges between 0 (normal) and 100 (severe disease symptoms); before the study started, people had a total OSDI score of at least 20, indicating moderate disease. After 29 days, patients who received Vevizye had a reduction in their OSDI score of 7.08, which was similar to the reduction of 5.37 seen in those who received the vehicle.

The second study also looked at the effects of Vevizye on people's level of discomfort, as measured using a standard eye dryness scale ranging between 0 and 100; people's score was at least 50 at the start of the study. After 29 days, people who received Vevizye had a reduction in their dryness score of 12.6, which was similar to the reduction of 13.7 seen in those who receive the vehicle.

What are the risks associated with Vevizye?

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

The most common side effects with Vevizye include instillation site reactions (such as pain or burning in the eye) which may affect up to 1 in 10 people and blurred vision which may affect up to 1 in 100 people. Instillation site reactions were more common in patients aged 65 years and above than in younger people.

Vevizye must not be used in people who have cancer, or a condition that could lead to cancer, in or around the eye. It must also not be used in people who have an active or suspected infection in or around the eye.

Why is Vevizye authorised in the EU?

Vevizye has been shown to reduce the signs of dry eye disease, including damage to the cornea, in people with moderate to severe dry eye disease that has not improved despite treatment with tear substitutes. Although these effects were not accompanied with symptom relief, such as a reduction in discomfort, compared with the vehicle, the benefits of treatment are considered clinically relevant. In terms of safety, the side effects of Vevizye were considered mild and short-lasting. The European Medicines Agency therefore decided that Vevizye's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Vevizye are continuously monitored. Suspected side effects reported with Vevizye are carefully evaluated and any necessary action taken to protect patients.

Other information about Vevizye

Vevizye received a marketing authorisation valid throughout the EU on 19 September 2024.

Further information on Vevizye can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vevizye.

This overview was last updated in 09-2024.