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EPAR summary for the public

Verkazia

ciclosporin

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

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

What is Verkazia and what is it used for?

Verkazia is a medicine used to treat severe vernal keratoconjunctivitis (VKC), an allergic condition that affects the eye and mostly occurs seasonally, although in some patients symptoms can recur or persist all year round. It is used in children and adolescents from 4 to 18 years of age.

Because the number of patients with vernal keratoconjunctivitis is low, the disease is considered 'rare', and Verkazia was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 April 2006.

Verkazia contains the active substance ciclosporin.

How is Verkazia used?

Verkazia can only be obtained with a prescription and treatment must be started by a healthcare professional qualified in ophthalmology (eye medicine).

Verkazia is available as eye drops. The recommended dose is 1 drop 4 times a day in each affected eye, during VKC season. If symptoms persist after the end of the season, Verkazia can continue to be used at the recommended dose until symptoms are under control and at a reduced dose (1 drop twice a day) thereafter.

For further information, see the package leaflet.

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How does Verkazia work?

The active substance in Verkazia, ciclosporin, blocks cells of the immune system (the body's natural defences) that are involved in the processes that cause the allergic reaction and inflammation in patients with VKC. Applying it directly to the eye reduces eye inflammation but limits its effects elsewhere in the body.

What benefits of Verkazia have been shown in studies?

Verkazia reduces damage to the cornea (layer in the front of the eye) in most patients with VKC as shown by improvements in 'corneal fluorescence staining' (CFS) scores (a standard measure of corneal health).

In a main study involving 169 children and adolescents with severe VKC, 55% of patients treated with Verkazia achieved CFS improvements of 50% or more, without the need of other medications, after 4 months, compared with around 28% of patients receiving a dummy treatment. Symptoms such as itching, fluid or mucous discharge and light sensitivity also improved in patients treated with Verkazia to a greater extent than with the dummy treatment. Some of the patients were treated for an additional 8 months; this extension study showed that the benefits of Verkazia were maintained with continued use for up to 12 months.

What are the risks associated with Verkazia?

The most common side effects with Verkazia are eye pain and itching, which may affect around 1 in 10 people. These symptoms usually occur when the drops are being put in the eyes and go away shortly after.

Verkazia must not be used in patients with active or suspected infections in or around the eye.

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

Why is Verkazia approved?

Verkazia has been shown to be effective at improving the condition of the cornea and reducing the symptoms of the disease. Side effects are mostly mild and disappear shortly after application of the medicine. The European Medicines Agency therefore decided that Verkazia'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 Verkazia?

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

Other information about Verkazia

The European Commission granted a marketing authorisation valid throughout the European Union for Verkazia on 6 July 2018.

The full EPAR for Verkazia 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 Verkazia, 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 Verkazia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 07-2018.