

## **Package leaflet: Information for the patient**

### **Verkazia 1 mg/mL eye drops emulsion** ciclosporin

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Verkazia is and what it is used for
2. What you need to know before you use Verkazia
3. How to use Verkazia
4. Possible side effects
5. How to store Verkazia
6. Contents of the pack and other information

#### **1. What Verkazia is and what it is used for**

Verkazia contains the active ingredient, ciclosporin. Ciclosporin reduces the activity of the body's immune (defence) system and in this way it reduces inflammation (body response to harmful stimuli).

Verkazia is used to treat children and adolescents aged 4 to 18 years with severe vernal keratoconjunctivitis (an allergic condition of the eye that occurs more frequently in spring and affects the transparent layer in the front part of the eye and the thin membrane covering the front part of the eye).

#### **2. What you need to know before you use Verkazia**

##### **Do not use Verkazia**

- if you are allergic to ciclosporin or to any of the other ingredients of this medicine (listed in section 6)
- if you have had or have a cancer in or around your eye.
- if you have an eye infection.

##### **Warnings and precautions**

Only use Verkazia in your eye as described under section 3. Do not exceed the treatment period prescribed by your doctor.

Verkazia has not been studied in adult patients.

Talk to your doctor or pharmacist before using Verkazia:

- if you have had an eye infection or if you suspect you have an eye infection
- if you have any other kind of eye disease
- if you wear contact lenses (the use of Verkazia is not recommended with contact lenses).

##### **Children and adolescents**

Do not use Verkazia in children under the age of 4 years.

### **Other medicines and Verkazia**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Talk to your doctor if you are using eye drops containing steroids administered in association with Verkazia as this association may increase the risk of local infections.

If you are using Verkazia for more than 12 months, you should visit your doctor regularly, e.g. every 3 to 6 months.

If you are using other eye drops, use Verkazia **at least 15 minutes** after using the other eye drops.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Verkazia should not be used if you are pregnant. If you could become pregnant you must use contraception while using this medicine.

Verkazia is likely to be present in breast milk in very small amounts. If you are breast feeding talk to your doctor before using this medicine.

### **Driving and using machines**

Your vision may be temporarily blurred after using Verkazia eye drops or you may get other disturbances with your vision. If this happens, wait until your vision clears before you drive or use machines.

### **Verkazia contains cetalkonium chloride**

Cetalkonium chloride may cause eye irritation.

## **3. How to use Verkazia**

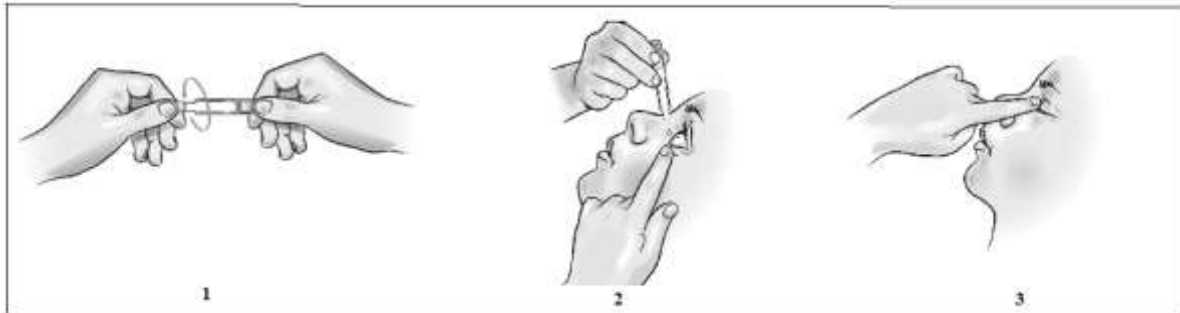
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A caregiver should help a child starting Verkazia treatment, particularly if the child is aged under 10 years, and should continue to supervise the child until the child is able to use Verkazia properly without help.

The recommended dose is 1 drop of Verkazia in each affected eye 4 times a day (morning, mid-day, afternoon and evening). You should continue Verkazia as prescribed by your doctor.

### **Instructions for use**

Follow these instructions carefully and ask your doctor or pharmacist if there is anything you do not understand.



1. Wash your hands
2. Open the aluminium pouch, which contains 5 single-dose containers
3. Take 1 single-dose container from the aluminium pouch, leaving the remaining containers in the pouch
4. Gently shake the single-dose container
5. Twist off the cap (**picture 1**)
6. Pull down your lower eyelid (**picture 2**)
7. Tilt your head back and look up at the ceiling
8. Gently squeeze one drop of the medicine onto your eye. Make sure that the tip of the single-dose container does not touch your eye
9. Blink a few times so that the medicine spreads across your eye
10. After using Verkazia, press a finger lightly on the inner corner of your eyelid, next to your nose for 2 minutes (**picture 3**). A small duct that drains tears away from your eye and into your nose is located here. By pressing at this point, you close down the opening of this drainage duct. This helps to stop Verkazia getting into the rest of the body.
11. If you use drops in both eyes, repeat the steps 6 to 9 for your other eye.
12. Discard the single-dose container as soon as you have used it, even if there is still some medicine left in it

If a drop misses your eye, try again.

**If you put in more Verkazia than you should**, rinse your eye with water. Do not put in any more drops until it is time for your next regular dose.

**If you forget to use Verkazia, continue with the next dose as planned.** Do not take a double dose to make up for the forgotten dose. Do not use more than 1 drop 4 times a day in the affected eye(s).

**If you stop using Verkazia** without speaking to your doctor, your eye allergy will not be controlled and could lead to long-term problems with your sight.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**The following side effects have been reported for Verkazia:**

The most common side effects are in and around the eyes.

**Very common side effects (may affect more than 1 in 10 people)**

Pain when the drops are put into the eye.

### **Common side effects (may affect up to 1 in 10 people)**

*Common side effects related to the eye:*

Itching, redness, irritation and discomfort in or around the eye including a feeling that there is something in the eye. Increased watering of the eye and blurred vision when the drops are put into the eye. Swelling and redness of eyelid.

*Common side effects which are not related to the eye:*

Upper respiratory tract infection, cough, headache.

### **Uncommon side effects (may affect up to 1 in 100 people)**

Swelling of the eyelid and of the conjunctiva (thin membrane covering the front part of the eye).

Bacterial infection of the cornea (transparent front part of the eye). Eye infection caused by herpes zoster virus.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see contact details below).

#### **Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

#### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Verkazia**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton, on the aluminium pouch label, and on the single-dose containers label after “EXP”. The expiry date refers to the last day of that month.

Do not freeze.

Store below 30°C.

Keep single-dose containers in the pouch in order to protect from light and avoid evaporation.

Discard the opened single-dose container immediately after use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Verkazia contains**

- The active substance is ciclosporin. One millilitre of Verkazia contains 1 mg of ciclosporin.
- The other ingredients are medium-chain triglycerides, cetalkonium chloride, glycerol, tyloxapol, poloxamer 188, sodium hydroxide (to adjust pH) and water for injections.

**What Verkazia looks like and contents of the pack**

Verkazia is a milky white eye drops emulsion.

It is supplied in single-dose containers made of a low-density polyethylene (LDPE).

Each single-dose container contains 0.3 mL eye drops emulsion.

The single-dose containers are wrapped in a sealed aluminium pouch.

Pack sizes: 30, 60, 90 and 120 single-dose containers.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**This leaflet was last revised in 03/2020.**

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.