

PACKAGE LEAFLET

Package leaflet: Information for the patient

Vevizye 1 mg/mL eye drops, solution 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Vevizye is and what it is used for

Vevizye contains the active substance ciclosporin. Ciclosporin belongs to a group of medicines known as immunosuppressants. These are medicines used to reduce inflammation.

Vevizye is used to treat adults with dry eye disease (including inflammation of the cornea, the transparent layer in front of the eye that covers the iris). It is used in patients whose disease has not sufficiently improved despite treatment with tear substitutes (artificial tears).

Treatment response generally occurs after 4 weeks of therapy, when the symptoms and ocular surface damage associated with dry eye disease are reduced.

2. What you need to know before you use Vevizye

Do not use Vevizye if you

- are allergic to ciclosporin or any of the other ingredients of this medicine (listed in section 6)
- have a cancer or precancerous condition in or around the eye
- have an infection in or around the eye

Warnings and precautions

The use of Vevizye eye drops has not been studied in people wearing contact lenses. If you wear contact lenses, remove them before using this medicine; you can reinsert them 15 minutes after you have used the eye drops. See section 3 How to use Vevizye.

You should visit your doctor after about 3 months of therapy start and thereafter about every six months to assess the effect of Vevizye. Tell your doctor if you have glaucoma and receive glaucoma therapy.

If you experience any signs of a local infection (redness, eye discharge) please contact your doctor.

Children and adolescents

Vevizye is not used in children and adolescents under 18 years.

Other medicines and Vevizye

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

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, pharmacist or nurse for advice before using this medicine.

Vevizye is not recommended during pregnancy, unless the benefit for the mother outweighs the potential risk for the unborn child.

Vevizye is not recommended when breast-feeding.

Driving and using machines

Your vision may be temporarily blurred immediately after using this medicine. If this happens, wait until your vision clears before you drive or use machines.

3. How to use Vevizye

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


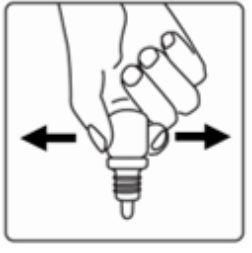
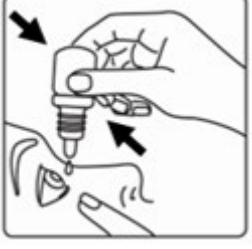
The recommended dose is 1 drop in each eye twice daily, approximately 12 hours apart.

Method of administration

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

- Wash your hands before using Vevizye.
- Do not use Vevizye if the tamper-evident ring of a new unopened bottle is not intact.
- After first opening, the tamper-evident ring of the cap remains on the bottle neck.
- The Vevizye dropper tip must not touch your eyes to avoid injury or contamination of the medicine; also keep the dropper tip from touching your fingers or other surfaces.
- If you are using Vevizye with other eye medicines, wait at least 15 minutes between using Vevizye and the other eye medicine.
- If you wear contact lenses, remove them before using Vevizye. Wait for at least 15 minutes after using the eye drops before placing them back in your eyes.

Administration

Step 1) Remove the white cap from the bottle	
Step 2) Gently squeeze the bottle in upright position and keep it squeezed	
Step 3) Turn the bottle upside down and release pressure	
Step 4) Tilt your head. Use your finger to pull down the lower eyelid. Squeeze bottle gently while still in upside down position to release one drop (0.01 mL) in the first eye	
Step 5) Repeat Step 4 for second eye	
Step 6) Place the white cap back on the bottle and keep the bottle tightly closed when not in use	

Due to the properties of the solution you may not feel when the drop falls into your eye. If it helps, you can use a mirror or ask another person to check when the drop is released from the dropper tip. Do not take a second drop because you did not feel the first falling into your eye. Only take another drop if the first misses your eye (for instance, when you feel it land on your skin).

If you use more Vevizye than you should

Do not put in any more drops into that eye until it is time for your next regular dose. If you have not done so, you can put an eye drop into your other eye.

If you forget to use Vevizye

Continue with the next dose as scheduled. Do not use a double dose to make up for the forgotten dose. Do not use more than 1 drop twice daily per eye.

If you stop using Vevizye

Do not stop treatment without talking to your doctor, as symptoms may return when you stop taking Vevizye.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects reported with Vevizye were transient and of mild intensity. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist.

Common (may affect up to 1 in 10 people)

- burning upon drop instillation in the eye (instillation site pain)

Uncommon (may affect up to 1 in 100 people)

- blurred vision
- eye irritation
- eye reddening (eye erythema)
- eye pain
- reduced clarity of vision (visual acuity reduced [temporarily])
- eye itching (pruritus)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: 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 Vevizye

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 bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not freeze or refrigerate.

This medicine can be used for up to 4 weeks after first opening of the bottle; after this discard this medicine, even if the bottle is not empty. The bottle must be kept tightly closed when not in use. Do not use this medicine if you notice signs of deterioration.

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 Vevizye contains

- The active substance is ciclosporin.
One mL of solution contains 1 mg of ciclosporin.
- The other ingredients are perfluorobutylpentane and ethanol anhydrous.

What Vevizye looks like and contents of the pack

Vevizye 1 mg/mL is a clear, colourless eye drops, solution.

Each multidose bottle contains 2 mL eye drops and each pack contains one bottle.

Marketing Authorisation Holder

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number 0345 521 1290.