

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vevye®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vevye®.**

Where to find information in this leaflet:

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1. Why am I using Vevye®?

Vevye® contains the active ingredient cyclosporin. Cyclosporin belongs to a group of medicines known as immunosuppressive agents that are used to reduce inflammation.

Vevye® is used to treat the signs and symptoms of moderate to severe dry eye disease in adult patients, which has not improved despite treatment with tear substitutes.

2. What should I know before I use Vevye®?

Warnings

Do not use Vevye® if:

- you are allergic to cyclosporin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have or have had a cancer in or around your eye.
- You have an eye infection.

Do not use Vevye® in adolescents and children under 18 years.

Check with your doctor if you:

- have any other medical conditions, in particular, any conditions which affect your eyes.
- take medicines for any other condition, particularly medicines used to treat eye disorders.
- if you have previously had an eye infection caused by the herpes virus that might have damaged the transparent front part of the eye (cornea).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Caution should be exercised when Vevye® is administered to pregnant or nursing women.

3. What if I am taking other medicines?

Tell your doctor, optometrist or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Vevye® can be used concomitantly with other eye drops, allowing a 15-minute interval between products.

4. How do I use Vevye®?

How much to take / use

Instill one drop (0.01 mL) of Vevye® twice a day in each eye approximately 12 hours apart.

Your doctor may prescribe a different dose for you as per your condition. Follow the instruction given to you by your doctor.

How to use Vevye®

Important information you need to know before applying Vevye®

- For topical use in the eye only.
- Do not use if the tamper-evident ring attached to the white cap is not intact.
- Do not let the Vevye® dropper tip touch your eye, fingers, or any other surfaces to avoid contamination or injury to your eye.
- Use 1 drop of Vevye® in each eye, 2 times each day, about 12 hours apart.
- If you are using Vevye® with other eye (ophthalmic) medicines, you should wait at least 15 minutes between using Vevye® and the other medicine.
- If you wear contact lenses, remove them before using Vevye®. Wait for at least 15 minutes before placing them back in your eyes.

Preparing to apply Vevye®

- Wash your hands before using Vevye®.
- After first opening the tamper-evident ring of the cap remains on the bottle neck.

Apply Vevye®

- Step-1: Remove white cap from the bottle.
- Step-2: Squeeze bottle gently in upright position (Figure A).



Figure A

- Step-3: Turn the bottle upside down and release pressure (Figure B)



Figure B

- Step-4: Tilt your head. Squeeze bottle gently while still in upside down position to instill one drop (0.01 mL) in the affected eye (Figure C)

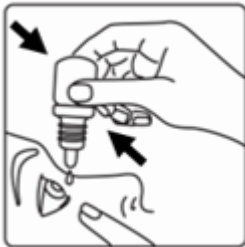


Figure C

- Step-5: Repeat Step 4 (Figure C) for second affected eye.
- Step-6: Place white cap back on the bottle and keep the bottle tightly closed when not in use.

If you use too much Vevye®

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Follow the same instructions as mentioned above if you think that you or anyone else may have swallowed any or all of the Vevye® eye drops.

5. What should I know while using Vevye®?

Things you should do

Remind any doctor, dentist, optometrist, or pharmacist you visit that you are using Vevye®.

Things you should not do

- Do not stop using this medicine without checking with your doctor or optometrist.
- Do not give Vevye® to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vevye® affects you.

Vevye® may cause blurred vision in some people. If this happens, wait until your vision becomes normal before you drive or use machines.

Looking after your medicine

- Store below 25 °C.
- Do not freeze or refrigerate.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard after 4 weeks of first opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Common: <ul style="list-style-type: none">• burning upon drop instillation in the eye (instillation site reactions)	Speak to your doctor if you have any of these less serious side effects and they worry you.
Uncommon: <ul style="list-style-type: none">• blurred vision• eye irritation	

<ul style="list-style-type: none"> • eye reddening (eye erythema) • eye pain • reduced clarity of vision (visual acuity reduced [temporarily]) • eye itching (pruritus) 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at <https://pophealth.my.site.com/carmreportnz/s/>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Vevye® contains

Active ingredient (main ingredient)	Cyclosporin
Other ingredients (inactive ingredients)	Perfluorobutylpentane Ethanol

Do not take this medicine if you are allergic to any of these ingredients.

What Vevye® looks like

Vevye® is a clear colourless solution packed in a polypropylene bottle fitted with a dropper and screw cap. One bottle is packed in a carton.

Who distributes Vevye®

AFT Pharmaceuticals Ltd.
Auckland, New Zealand.
Toll free phone: 0800-423-823
Email: customer.service@aftpharm.com

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