

Cequa 0.9 mg/mL eye drops, solution in single-dose container

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

1. What Cequa is and what it is used for

Cequa contains the active substance, ciclosporin. Ciclosporin belongs to a group of medicines known as immunosuppressive agents that are used to reduce inflammation.

Cequa is used to treat moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients who have not responded adequately to artificial tears.

Talk to a doctor if you do not feel better or if you feel worse.

You should visit your doctor at least every 3 months to assess the effect of Cequa.

2. What you need to know before you take use Cequa

Do not use Cequa

- if you are allergic to ciclosporin or 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 Cequa for dropping in your eye(s).

Talk to your doctor or pharmacist before using Cequa

- If you have had an eye infection by herpes virus that might have damaged the transparent front part of the eye (cornea),

- if you are taking any medicines containing steroids,
- if you are taking any medicines to treat glaucoma.

You should remove your contact lenses before using Cequa; you can insert them again 15 minutes after the administration of Cequa.

Children and adolescents

Cequa should not be used in children and adolescents below the age of 18 years.

Other medicines and Cequa

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, as these might increase the risk of side effects.

Cequa eye drops should be used at least 15 minutes after any other eye drops is used.

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 taking this medicine.

Cequa should not be used if you are pregnant.

If you could become pregnant you must use contraception while using this medicine.

Cequa 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 blurred immediately after using Cequa eye drops, solution in single-dose container. If this happens, wait until your vision clears before you drive or use machines.

Cequa contains phosphates

This medicine contains 0.159 mg phosphates in each drop. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

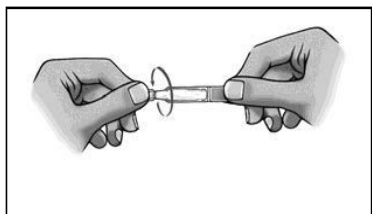
3. How to use Cequa

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 one drop in each affected eye, twice daily, approximately 12 hours apart.

Instructions for use

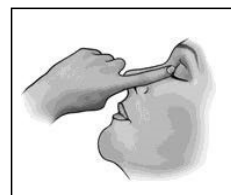
Follow these instructions carefully and ask your doctor or pharmacist if there is anything you do not understand.



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- Wash your hands.
- If you wear contact lenses, take them out before using the drops; you can reuse them 15 minutes after you have administered the eye drops.
- Open the aluminium pouch, take one single-dose container out, and put the remaining single-dose containers back in the pouch
- Twist off the cap (**picture 1**).
- Pull down your lower eye lid (**picture 2**).
- Tilt your head back and look up to the ceiling.
- Gently squeeze one drop of the medicine onto your eye. Make sure you do not touch your eye with the tip of the single-dose container.
- Blink a few times to distribute the eye drop over your eye.
- After applying the drop, press a finger into the corner of your eye by the nose and close the eyelids gently for app. 2 minutes (**picture 3**) (this helps the local effect).
- If you use drops in both eyes, repeat the steps for your other eye.
- Discard the single-dose container as soon as you have used it, even if there is still some liquid left in it.
- The remaining single-dose containers should be kept in the aluminium pouch.

If a dropped missed the eye, try again.

If you use more Cequa 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 Cequa, continue with the next dose as planned.

Do not take a double dose to make up for a forgotten dose. Do not use more than one drop at a time in the effected eye (s).

If you stop using Cequa, discuss this with your doctor.

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:

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

Very common (may affect more than 1 in 10 people): pain or discomfort when you first put a drop in.

Common (may affect up to 1 in 10 people): eye redness, eye irritation, watering of the eye, irritation in the eye.

Uncommon (may affect up to 1 in 100 people): increased watering of the eye, increased sensitivity to light, eye pain, swelling of the conjunctiva (skin covering the white of the eye), inflammation of the lid margins, ocular and periocular infections, headache, and throat irritation.

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 at: 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 Cequa

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, the aluminium pouch and on the single-dose containers after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. After opening of the aluminium pouches, the single-dose containers should be kept in the pouches in order to avoid evaporation. Shelf life after first opening of the aluminium pouch: 5 days. Discard any opened individual single-dose container with any remaining solution immediately after use.

Do not use this medicine if you notice visible particles.

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 Cequa contains

- The active substance is ciclosporin. One milliliter of Cequa contains 0.9 mg of ciclosporin.
- The other ingredients are: Macrogolglycerol hydroxystearate, octoxynol-40, sodium dihydrogen phosphate dihydrate (E339), disodium phosphate (E339), sodium chloride, povidone (E1201), hydrochloric acid (for pH adjustment) (E507), sodium hydroxide (for pH adjustment) (E524) and water for injection.

What Cequa looks like and contents of the pack

Cequa is a clear, colourless solution in single-dose container.
It is supplied in single-dose containers made of a low-density polyethylene (LDPE).
Each single-dose container contains 0.25 mL eye drops, solution.
The single dose containers are wrapped in a sealed polyfoil aluminium pouch.

Pack sizes: 60 single-dose containers.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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