

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Cequa

Ophthalmic solution (0.09%)

Active ingredient: cyclosporine 0.9 mg/ml

Inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Cequa is indicated to increase tear production in patients with dry eye syndrome (keratoconjunctivitis sicca).

Therapeutic group: Agents locally affecting the immune system.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

To avoid the possibility of eye injury and contamination, be careful not to allow the vial tip touch the eye or other surfaces.

Do not use Cequa while wearing contact lenses. Generally, contact lenses should not be worn by patients with decreased tear production. If contact lenses are worn, they should be removed prior to using this medicine. Lenses may be reinserted 15 minutes following administration of medicine into the eye.

Children and adolescents

There is no information about the safety and efficacy of this medicine in children and adolescents below the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

Pregnancy

Before you receive Cequa, tell your doctor if you are pregnant or are planning to become pregnant.

There is no information regarding use of this medicine during pregnancy.

Do not use the medicine without consulting your doctor before starting treatment if you are pregnant or are planning to become pregnant while using the medicine.

Breastfeeding

Before you receive Cequa, tell your doctor if you are breastfeeding or are planning to breastfeed.

Cyclosporine blood concentration is low following topical ocular administration of Cequa. There is no information regarding passage of cyclosporine into breast milk following topical administration or regarding the effect of Cequa on the breastfed infant and milk production. Your doctor will consider the benefits of breastfeeding against the clinical need for treatment with Cequa and any possibility of side effects in the breastfed infant.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine. Only your doctor will determine your dose and how you should use this medicine.

The recommended dosage is usually one drop in each eye, twice daily, about 12 hours apart.

Cequa can be used with artificial tears (lubricating eye drops). In such case, wait about 15 minutes between them.

Use the vial content immediately after opening for administration to one or both eyes. Discard the vial immediately after administration and do not re-use it.

Do not exceed the recommended dose.

Attention – do not swallow! The medicine is intended for external use only.

If you have accidentally taken a higher dose

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Cequa may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects:

Pain during instillation of the drops (an effect which occurred in 22% of users)

Conjunctival hyperemia (excess blood in the blood vessels) (an effect which occurred in 6% of users)

Common side effects: (effects which occurred in 1% to 5% of users)

Blepharitis, eye irritation, headache and urinary tract infection

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/ vial.

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

Storage conditions

Do not store above 25°C. Store the single-use vials in the original aluminum pouch.

6. Additional information

In addition to the active ingredient this medicine also contains:

Polyoxyl 40 hydrogenated castor oil, sodium phosphate monobasic dihydrate, sodium phosphate dibasic anhydrous, Octoxynol-40, polyvinylpyrrolidone, sodium chloride, water for injection, and sodium hydroxide or hydrochloric acid to adjust pH.

What the medicine looks like and contents of the pack:

Cequa ophthalmic solution is packed in single-use vials. Each vial contains 0.25 ml solution. Each pack contains 60 vials, with each 10 vials packed in a multi-layered aluminum pouch; 6 pouches are packed in a box.

Registration holder's name and address: Taro International Ltd., Hakitor St. 14, Haifa Bay 2624761

Manufacturer's name and address:

Laboratoire UNITHER, 1 rue de l'Arquerie, 50200 Coutances, France

The leaflet was approved in April 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 165-76-36091