

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

CEQUA™ Ciclosporin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CEQUA eye drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CEQUA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CEQUA eye drops are used for

CEQUA is used to treat a condition known as 'keratoconjunctivitis sicca' which is also known as 'dry eye'. When you have this condition, your tear glands do not produce enough tears and your eyes can become dry, red and irritated.

Your doctor will give you CEQUA if you have this condition and treatment with tear substitute medicines alone have not worked.

CEQUA belongs to a group of medicines called immunosuppressants. It works by reducing inflammation and increasing tear production so that your eyes are better lubricated.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

CEQUA is not addictive.

CEQUA is available only with a doctor's prescription.

CEQUA is not expected to affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you use CEQUA eye drops

When you must not use it

Do not use CEQUA if you have an allergy to:

- any medicine containing ciclosporin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine if you are pregnant.

Do not use this medicine if you have an eye infection or think you may have an eye infection.

Do not use this medicine if you have a cancer of the eye or around the eye.

Possible effects of CEQUA on a developing baby have not been studied and are unknown.

Do not breast-feed if you are taking this medicine.

Possible effects of CEQUA on a breast-feeding baby have not been studied and are unknown.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not use CEQUA after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking CEQUA, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you use contact lenses as you must not use CEQUA while you are wearing contact lenses. Your contact lenses must be removed before you use CEQUA and may be reinserted 15 minutes after using CEQUA.

Tell your doctor if you are using artificial tears as you must not apply artificial tears at the same time as CEQUA. You can apply artificial tears 15 minutes after applying CEQUA.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using CEQUA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food store.

Some medicines and CEQUA may interfere with each other. These include:

- other eye drops.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use CEQUA eye drops

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

One drop of CEQUA twice daily (about 12 hours apart) into each eye. You can use other artificial tears eye drops but you should wait at least 15 minutes after applying CEQUA.

How to use it

If you are wearing contact lenses, remove them first and wait at least 15 minutes after using CEQUA before reinserting.

Detach the ampoule from the connecting plastic strip and then twist the top off the plastic ampoule.

Tilt your head back and squeeze one drop into each eye.

To avoid injury, be careful not to touch your eye with the tip of the ampoule.

Immediately discard the ampoule after each use. Do not store any opened CEQUA ampoules.

When to use it

As CEQUA should not be used more than twice a day and use should be about 12 hours apart, a morning and evening application is recommended.

Using it at the same times each day may help you remember when to use it.

It does not matter if you use this medicine before or after food.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it.

If you forget to use it

If it is less than about 12 hours before your next dose, skip the dose you missed and use your next dose when you are meant to.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

It is unlikely that you will use too much CEQUA, however, if you or anyone else has, or you or anyone else has accidentally swallowed CEQUA, telephone your doctor or the Poisons Information Centre at 13 11 26 (Australia) and 0800 764 766 (New Zealand) for advice or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using CEQUA eye drops

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CEQUA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking CEQUA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking CEQUA.

It may affect other medicines used during surgery.

If you become pregnant while taking CEQUA, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking CEQUA.

Keep all your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use CEQUA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen. If possible, your doctor will reduce the amount you use each day.

Do not store any opened CEQUA ampoules.

Things to be careful of

If you are wearing contact lenses, remove them first before applying CEQUA.

To avoid injury, be careful not to touch your eye with the tip of the ampoule.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CEQUA.

This medicine helps most people with your condition, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- pain, stinging or itchiness in your eye that persists after you add the drops to your eyes
- persistent red or bloodshot eyes.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If you suffer from damage to the clear layer at the front of your eye (the cornea), the phosphates in CEQUA may very rarely cause cloudy patches on your eye. Tell your doctor if you notice this.

Tell your doctor as soon as possible if you notice any of the following:

- light sensitivity and/or blurred vision.

This could indicate a serious side effect that may require medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using CEQUA eye drops

Storage

Keep your medicine in the foil pouch until you want to use it.

The ampoules may not keep well out of the foil pouch.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not freeze.

Do not store your medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CEQUA is a clear, colourless liquid in soft plastic ampoules connected in cards of 5 ampoules. Two cards are enclosed in a sealed foil pouch and there are 6 foil pouches in a carton (60 ampoules per carton).

Ingredients

Each CEQUA ampoule contains 225 micrograms of ciclosporin as the active ingredient plus the following excipients:

- PEG-40 hydrogenated castor oil
- octoxinol 40
- povidone
- dibasic sodium phosphate
- monobasic sodium phosphate dihydrate
- sodium chloride
- water for injections
- sodium hydroxide or hydrochloric acid to adjust pH.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This medicine is preservative free.

Supplier

CEQUA is supplied in Australia by:

Sun Pharma ANZ Pty Ltd

ABN 17 110 871 826

12 Waterloo Road

Macquarie Park Sydney NSW 2113

Telephone: 1800 726 229

Email: customerservice.aus@sunpharma.com

AUST R number 313780

CEQUA is sponsored in New Zealand by:

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