

Package leaflet: Information for the patient

Cystadrops 3.8 mg/mL eye drops solution cysteamine (mercaptamine)

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 Cystadrops is and what it is used for
2. What you need to know before you use Cystadrops
3. How to use Cystadrops
4. Possible side effects
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1. What Cystadrops is and what it is used for

What Cystadrops is

Cystadrops is an eye drops solution that contains the active substance cysteamine (also known as mercaptamine).

What it is used for

It is used to reduce the quantity of cystine crystals in the surface of the eye (cornea) in adults and children from 2 years of age with cystinosis.

What is cystinosis

Cystinosis is a rare hereditary disease in which the body is unable to remove excess cystine (an amino acid), causing cystine crystals to accumulate in various organs (such as kidney and eyes). Accumulation of crystals in the eye can lead to increased sensitivity to light (photophobia), corneal deterioration (keratopathy) and loss of vision .

2. What you need to know before you use Cystadrops

Do not use Cystadrops

If you are allergic to cysteamine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Cystadrops.

Other medicines and Cystadrops

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

Pregnancy and breast-feeding

Even if the level of Cystadrops in the blood is negligible, precautions should be taken.

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.

Driving and using machines

You may find that your vision is blurred for a few minutes just after using Cystadrops. Do not drive or use machines until your vision is clear.

Cystadrops contains benzalkonium chloride

This medicine contains 5 micrograms benzalkonium chloride in each drop which is equivalent to 0.1 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Cystadrops

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

Recommended dose

- The recommended dose is 1 drop in each eye, 4 times a day during waking hours.
- The recommended interval between each application is 4 hours (for example, you can have your eye drops at 8.00 am, 12.00 am, 4.00 pm and 8.00 pm).
- To avoid sticky eyes in the morning, it is recommended to apply the last drop of the day at least 30 minutes before going to bed.
- The dose may be gradually decreased (to a minimum total daily dose of 1 drop in each eye) by your doctor based on eye examinations.

Only use the drops in your eyes (ocular use).

To use the eye drops, please follow the instructions below carefully. Those instructions are also available as an animated movie on www.cystadrops.net 'QR code to be included'

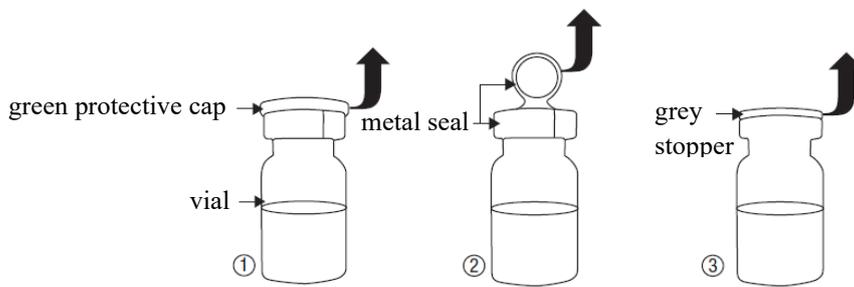
Step 1: Before using a vial for the first time

- Cystadrops must be brought back at room temperature before the first administration. It will facilitate the use of the drops.
- Immediately before using a vial for the first time, write the date of opening in the space provided on the carton box.
- Wash your hands carefully in order to avoid contamination by bacteria of the content in the vial.
- Remove the green protective cap (picture 1).
- Remove the metal seal (picture 2).
- Remove the grey stopper (picture 3) from the vial.
- Do not touch the opening of the vial after removing the grey stopper.

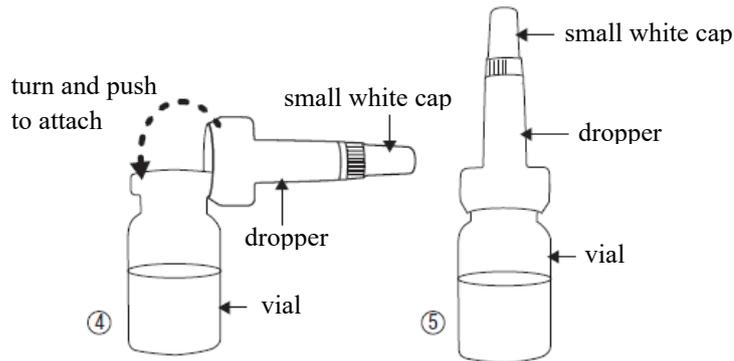
remove

remove

remove



- Take the dropper out of its sachet, without touching the end intended to be attached to the vial, and attach it (picture 4) to the vial. Do not remove the dropper from the vial.



- Make sure that you do not lose the small white cap (picture 5) that comes on the top of the dropper.

Step 2: Before using the eye drops

- Check the opening date that you wrote down on the carton box. Cystadrops can be used for up to 7 days from the time of opening.
- Get the dropper bottle and a mirror.
- Wash your hands.

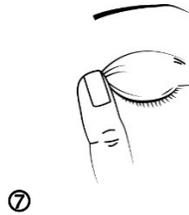
Step 3: Using the eye drops

- Hold the dropper bottle, pointing down, between your thumb and fingers. Move firmly the dropper bottle up and down to facilitate the filing of the dropper.
- Unscrew the small white cap from the dropper.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a “pocket” between the eyelid and your eye. The drop will go in here (picture 6).

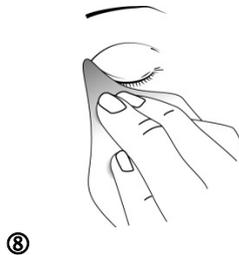


- Bring the dropper bottle tip close to the eye. Use the mirror if it helps.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops.

- Gently squeeze the dropper to release one drop of Cystadrops at a time. Take special care not to touch the tip of the dropper with your fingers.
- After using Cystadrops, press a finger into the corner of your eye by the nose (picture 7), then gently massage your upper eyelid to spread the eye drops over the eye.



- To avoid potential irritation, remove excess medicine around the eye with a moist tissue (picture 8).
- Repeat the step 3 for the other eye.
- Replace the small white cap on the dropper immediately after use.



Step 4: Storing the eye drops after use

- Place the dropper bottle into the carton box.
- Keep Cystadrops at room temperature (it will facilitate the use of the dropper).
- **Discard 7 days after opening.**

If a drop misses your eye

Try again.

If you use Cystadrops with another eye medicine

Ensure that there is at least a 10 minute gap between using Cystadrops and the other eye medicine. Administer eye ointments last.

If you wear soft contact lenses

Do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

If you use more Cystadrops than you should

If you put too many drops in your eyes, rinse your eyes out, preferably with saline solution (or if not available with warm water). Do not put in any more drops until it is time for your next regular dose.

If you forget to use Cystadrops

Wait for your next scheduled application and then continue with your regular routine. Do not use a double dose to make up for a forgotten dose.

If you stop using Cystadrops

Cystadrops must be used every day for the medicine to work properly. If you stop using Cystadrops, cystine crystals accumulation in the eye (cornea) may increase and lead to increased sensitivity to light (photophobia), corneal deterioration (keratopathy) and loss of vision. Therefore talk to your doctor before stopping this treatment.

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.

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using Cystadrops without speaking to your doctor.

The following side effects were reported:

Very common side effects (may affect more than 1 in 10 people)

- eye pain
- eye redness, eye itching, eye irritation (burning)
- watery eyes
- blurred vision
- discomfort where the drops have been instilled (mainly sticky eyes and sticky eyelashes), medicine deposit on the eyelashes, around the eyes

Common side effects (may affect up to 1 in 10 people)

- abnormal sensation in eye, a feeling of something in the eye
- dry eyes
- swollen eyelid
- irritation of eyelid
- visual impairment
- pain where the drops have been instilled
- stye

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

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 Cystadrops

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 vial label and the carton after EXP. The expiry date refers to the last day of that month.

Before opening:

- Store in a refrigerator (2°C - 8°C).
- Keep the vial in the outer carton in order to protect from light.

After first opening:

- Write down the date you opened the vial in the space on the carton.
- Cystadrops can be used for up to 7 days from the time of opening.
- Keep the dropper bottle tightly closed in the outer carton in order to protect from light.
- Store below 25°C.
- Do not refrigerate.

- **You must throw away the dropper bottle 7 days after you first opened it even if it is not empty.** Use a new vial.

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 Cystadrops contains

- The active substance is cysteamine (mercaptamine), as hydrochloride. One mL of eye drops solution contains 3.8 mg of cysteamine.
- The other ingredients are benzalkonium chloride (see section 2 under ‘Cystadrops contains benzalkonium chloride’), disodium edetate, carmellose sodium, citric acid monohydrate, sodium hydroxide, hydrochloric acid and water for injections.

What Cystadrops looks like and contents of the pack

Cystadrops is a clear and viscous eye drops solution.

Each box contains:

- 1 amber glass vial containing 5 mL of eye drops solution,
- 1 dropper applicator.

Cystadrops is available in pack containing 1 box or in multipack containing 4 boxes.

Not all pack sizes may be marketed in your country

Marketing Authorisation Holder

Recordati Rare Diseases
Immeuble “Le Wilson”
70 Avenue du Général de Gaulle
92800 Puteaux
France

Manufacturer

Recordati Rare Diseases
Immeuble “Le Wilson”
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92800 Puteaux
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or

Recordati Rare Diseases
Eco River Parc
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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