

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

CYSTADROPS®
Cysteamine Ophthalmic Solution
0.37 % w/w cysteamine (as cysteamine hydrochloride)

Read this carefully before you start taking **CYSTADROPS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CYSTADROPS**.

What is CYSTADROPS used for?

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

How does CYSTADROPS work?

Cystinosis is a rare disease where naturally occurring cystine builds up in body organs and tissues including the surface of the eye (cornea). **CYSTADROPS** changes cystine so that it does not build up in the cornea.

What are the ingredients in CYSTADROPS?

Medicinal ingredients: cysteamine hydrochloride (also called mercaptamine hydrochloride)
Each mL of **CYSTADROPS** contains 3.8 mg cysteamine (as cysteamine hydrochloride)

Non-medicinal ingredients: benzalkonium chloride (as a preservative), carmellose sodium, citric acid monohydrate, disodium edetate, hydrochloric acid, sodium hydroxide, water for injections.

CYSTADROPS comes in the following dosage form:

- a viscous (thick) solution to use as eye drops.

Do not use CYSTADROPS if:

- you are allergic to cysteamine or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CYSTADROPS. Talk about any health conditions or problems you may have, including if you:

- are using, have recently used, or might use any other eye drops.
- are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.
- wear soft contact lenses.

Other warnings you should know about:

- **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.

- **Soft Contact Lenses:** Benzalkonium chloride (a preservative in CYSTADROPS) may cause eye irritation and is known to discolour soft contact lenses. If you wear soft contact lenses, remove them before using CYSTADROPS. Wait at least 15 minutes after using CYSTADROPS before putting your contact lenses back in.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take CYSTADROPS:

Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Usual dose:

- Use 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 use your eye drops at 8.00 am, 12.00 am, 4.00 pm and 8.00 pm).
- To avoid sticky eyes in the morning, 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.

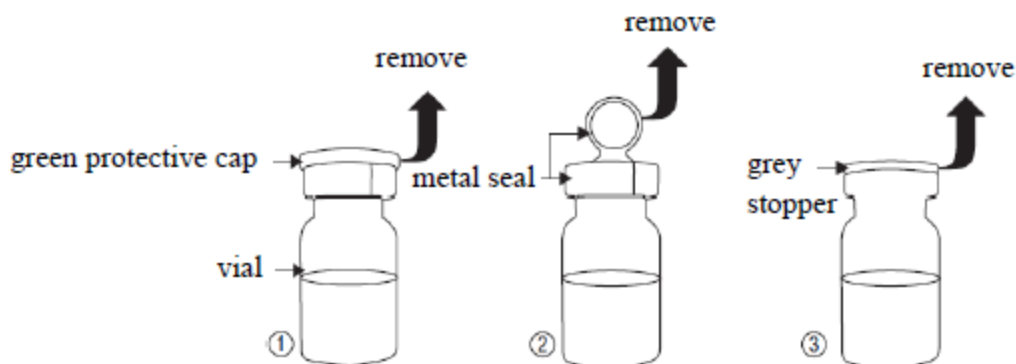
Only use the drops in your eyes (ocular use).

Before opening, store CYSTADROPS in a refrigerator (2°C - 8°C).

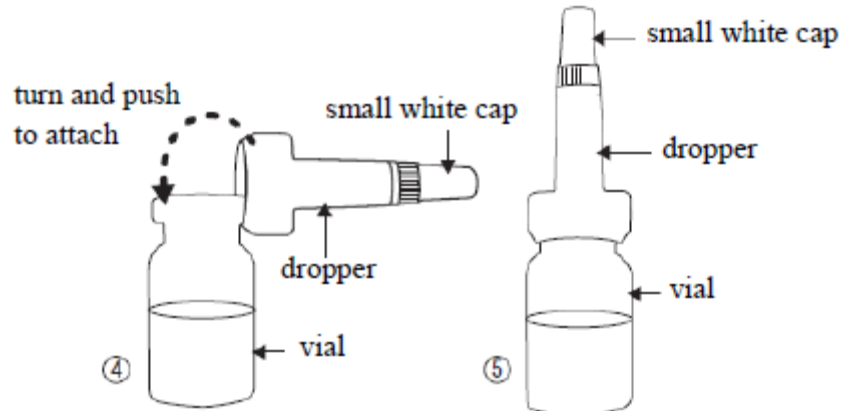
To use the eye drops, please follow the instructions below carefully:

Step 1: Before using a vial for the first time

- CYSTADROPS must be brought to room temperature before the first administration. This will make it easier to instill the drops.
- Immediately after opening 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 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.



- 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.



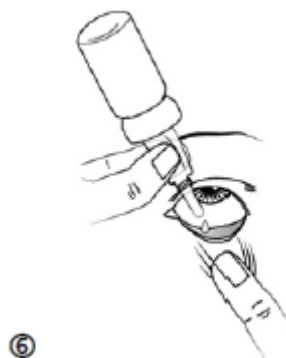
- Make sure that you do not lose the small white cap (picture 5) that comes on the top of the dropper.

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 filling 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).

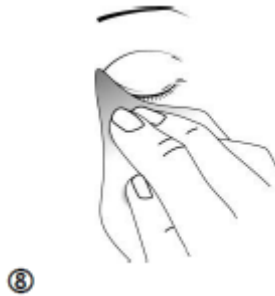


- Bring the dropper bottle tip close to the eye. Use the mirror if it helps.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops.
- Gently squeeze the dropper to release one drop of CYSTADROPS.
- **If a drop misses your eye, try again.**
- 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 drop over the eye.



- To avoid potential irritation, remove excess medicine around the eye with a moist tissue (picture 8).
- Repeat 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 (which will make it easier to use the dropper).
- **Discard 7 days after opening.**

If you use CYSTADROPS with another eye medicine:

Use the other eye medicine at least 10 minutes before or 10 minutes after you use CYSTADROPS. Administer eye ointments last.

If you wear soft contact lenses:

Do not use the drops with your soft contact lenses in. Remove your contact lenses. After using CYSTADROPS, wait 15 minutes before putting your contact lenses back in.

Overdose:

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 think you have taken too much CYSTADROPS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of 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) can increase. Therefore talk to your doctor before stopping this treatment.

What are possible side effects from using CYSTADROPS?

These are not all the possible side effects you may feel when taking CYSTADROPS. If you experience any side effects not listed here, contact your healthcare professional.

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.

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Keratitis (inflammation of cornea): eye redness, eye pain, excess tearing, blurred vision, decreased vision, increased sensitivity to light, a feeling that something is in your eye; <i>in presence of keratitis, these symptoms are continual and do not occur just when CYSTADROPS are instilled.</i>			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight 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 at room temperature (up to 25°C).
- Do not put your dropper bottle back in the refrigerator.
- **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.

If you want more information about CYSTADROPS:

- Talk to your healthcare professional
 - Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the Canadian distributor's website <http://www.recordatirarediseases.ca/>, or by calling 905-827-1300.

This leaflet was prepared by Recordati Rare Diseases Canada Inc.

Last Revised February 6, 2019