

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

This medicine is dispensed with a doctor's prescription only

## **Cystadrops 3.8 mg/ml Eye drops**

Active ingredient and quantity:

**Each 1 ml contains 3.8 mg cysteamine (mercaptamine)**

Inactive ingredients and allergens in the preparation - see section 6 '**Additional information**'. See also '**Important information about some of this medicine's ingredients**' in section 2.

**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 to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

### **1. What is this medicine intended for?**

Cystadrops is indicated for the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis.

**Therapeutic group** - eye preparations

Cystinosis is a rare hereditary disease in which the body is unable to remove excess cystine (an amino acid). This causes 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. Before using the medicine**

**Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient (cysteamine) or to any of the other ingredients in this medicine (see section 6 - "**Additional information**").

**Special warnings about using this medicine**

**Contact lenses** - Contact of the medicine with contact lenses should be avoided. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

**Children and adolescents**

Cystadrops may be used in children from 2 years of age at the same dose as in adults.

**Drug interactions**

**If you are taking, have recently taken or if you may take other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.**

Wait at least 10 minutes between using Cystadrops and instilling other eye drops. Administer eye ointments last.

### **Pregnancy, breastfeeding and fertility**

Even if the level of Cystadrops in the blood is negligible, precautions should be taken. If you are pregnant or breastfeeding, 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**

Do not drive or use machines immediately after using the medicine as your vision may be blurred. Do not drive or use machines until your vision is clear.

Caution children against riding a bicycle, playing near a road, and similar activities.

### **Important information about some of this medicine's ingredients**

Cystadrops 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 an abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

### **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 take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually:

- One 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.

See the instructions at the end of the leaflet.

### **Do not exceed the recommended dose.**

### **Treatment duration**

Use Cystadrops regularly, without taking a break.

### **How to use**

Do not swallow.

For external use only. The preparation is to be used **as eye drops only**.

**If a drop misses your eye** - try again.

**If you have accidentally used a higher dose** and 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 a child has accidentally swallowed some medicine, refer immediately to a doctor or 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 regular time and continue with your regular routine. The treatment should be continued as recommended by your doctor.

#### **If you stop taking this medicine**

Cystadrops must be used every day to ensure the efficacy of the medicine.

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, 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 medicine. Wear glasses if you need them.**

**If you have any further questions on the use of this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

Like with all medicines, using Cystadrops may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of 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** - affect more than 1 in 10 users

- eye pain
- eye redness, eye itching, eye irritation (burning sensation).
- 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** affect 1-10 users out of 100

- 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

**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.**

## **Report 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](http://www.health.gov.il)) which links to an online form for reporting side effects, or by the following 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:**

#### **Before opening**

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

#### **After first opening**

- Write down the date you first 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 and use a new vial.**

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

## **6. Additional information**

In addition to the active ingredient, this medicine also contains:

Hydrochloric acid 1M, carmellose sodium (Blanose 12M31P), citric acid monohydrate, sodium hydroxide, disodium edetate, benzalkonium chloride 50% solution, sodium hydroxide 1M, water for injections.

### **What the medicine looks like and contents of the pack:**

Cystadrops is provided as a clear and viscous eye drops solution

Each box contains:

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

**Registration holder's name and address:** Medison Pharma Ltd., 10 Hashiloach Street, POB 7090, Petach Tikva

**Manufacturer's name and address:**

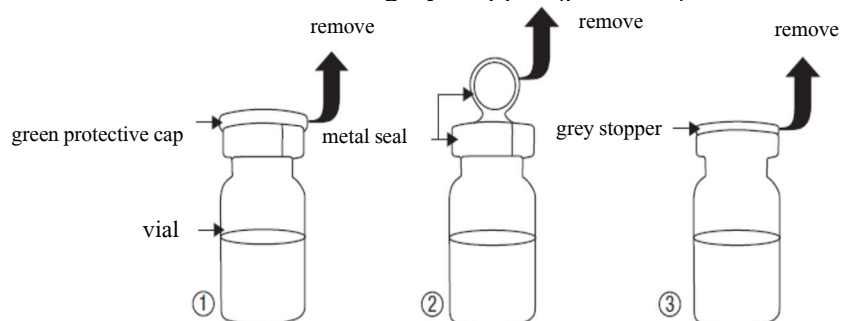
Recordati Rare Diseases  
Immeuble "Le Wilson"  
70, Avenue du Général de Gaulle  
92800 Puteaux  
France

This leaflet was revised in February 2021 according to MOH guidelines

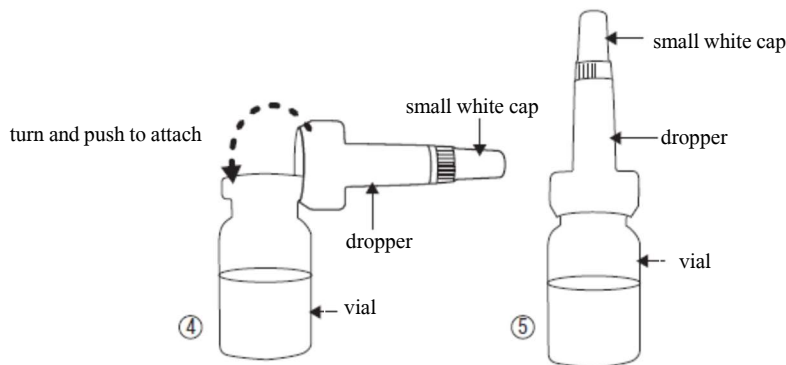
Registration number of the medicine in the Ministry of Health's National Drug Registry:  
164-69-35476

**Instructions for use****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.
- 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.

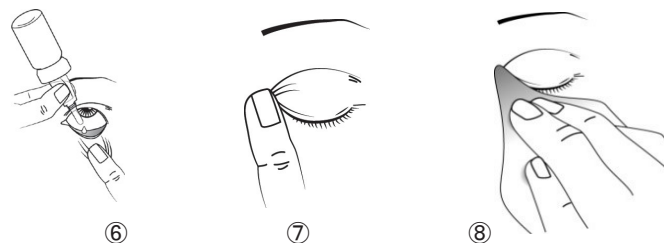


### Step 2: Before using the eye drops

- 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. Instil the medicine into the “pocket” created (picture 6).
- Bring the dropper bottle tip close to the eye. Use a mirror if needed.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could contaminate 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 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**

- Keep the dropper bottle in the carton box.
- Keep Cystadrops at room temperature - below 25°C (it will facilitate the use of the dropper).
- **Discard 7 days after opening the bottle.**

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