

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

This medicine is dispensed without a doctor's prescription.

Cromo-Comod Eye drops 2% w/v

Active ingredient

cromoglicic acid (as sodium) 20 mg/ml

For a list of the inactive ingredients, please see 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, refer to your doctor or pharmacist.

You must use this medicine according to the instructions in the dosage section in this leaflet. Consult your pharmacist if you need additional information. You should consult your doctor if your symptoms worsen or do not improve after two days.

1. What is this medicine intended for?

This medicine is intended as a preventive treatment for all types of allergic conjunctivitis.

Therapeutic group: The active ingredient belongs to the anti-allergy group of medicines.

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (cromoglicic acid) or to any of the other ingredients in this medicine (see section 6). Signs of an allergic reaction include: Rash, difficulty swallowing or breathing, swelling of the lips, face, throat, tongue and a worsening in the redness, itchiness or swelling of the eye or eyelid.

Special warnings about using this medicine

Before starting the treatment, you must be certain that the irritation in your eyes is the result of an allergy. If you are uncertain, you should consult your doctor before starting treatment. Do not wear contact lenses while using this medicine and for at least 15 minutes after use.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist, especially if you are taking other medicines used in the eyes.

Pregnancy and breastfeeding:

If you are pregnant, planning to become pregnant or think you may be pregnant or if you are breastfeeding or planning to breastfeed, do not use this medicine before you consult your doctor.

Driving and using machines:

Your vision may be blurred immediately after using the medicine. In that case, do not drive or operate dangerous machinery until your vision clears.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually 1 drop in each eye, 4 times a day at set intervals. The maximum dosage is 8 drops a day.

Do not exceed the recommended dose.

Use Cromo-Comod eye drops regularly to ensure optimal treatment of the symptoms of the allergic inflammation. It is recommended to continue treatment throughout the period of exposure to the allergen, even if symptoms have not appeared.

If your condition does not improve or worsens, refer to your doctor.

Use this medicine at set intervals.

Do not swallow. For external use only.

Instructions for use

A. To avoid contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle tightly closed.

B. How to use the drops:

1. Shake well before use.
2. Wash your hands thoroughly.
3. Tilt your head or lie down on your bed.
4. Using a finger, pull your lower eyelid slightly away from the eye. Carefully instill 1-2 drops into the pocket created. Make sure that the tip of the bottle does not come into contact with the eye.
5. Release the lower eyelid and blink several times to ensure that the liquid is fully distributed over the eye.
6. Make sure to close the cap of the bottle immediately after use.
7. Repeat the process in the other eye as well, if necessary.

If you think that the drop did not remain in the eye, use another drop.

Use a tissue to clean the remaining solution around the eye.

If you have used more Cromo-Comod than you should have:

Contact a doctor if you have used the eye drops more often than recommended.

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 forgot to take the medicine at the appropriate time, use the drops as soon as you remember. However, if you remember at a time close to that of the next dose, skip the forgotten dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking this medicine:

Even if the symptoms of the disease have improved, you must continue to use these drops if you are still in an environment containing the substances to which you are allergic. Cromo-Comod may prevent an allergic reaction, so if you stop the treatment, the allergy signs may return.

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 about using this medicine, consult your doctor or pharmacist.

4. Side effects:

Like with all medicines, using Cromo-Comod may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor as soon as possible if the stinging, redness or swelling worsens. You may be allergic to the medicine.

Consult a doctor or pharmacist if the following side effects worsen or persist for more than several days or if you notice any side effect not mentioned in this leaflet:

- Stinging and burning in the eyes or blurred vision. These side effects should only last a short time and should appear immediately after using the drops.
- Mild irritation of the eye.

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.

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

Storage conditions: Store below 25°C.

After first opening the bottle, it may be used for 12 weeks.

Do not store different medicines in the same package.

6. Additional information

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

Sorbitol, sodium edetate, water for injection.

What the medicine looks like and contents of the pack:

10 ml clear, colorless to yellowish solution in a bottle.

Manufacturer's name and address:

Ursapharm Arzneimittel GmbH

Industriestrasse, D-66129 Saarbrücken, Germany.

Registration holder's name and address:

Kivema Ltd., 33 Hachosh Street, Kfar Shmaryahu 46910.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1339031040.