PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

C R O M O L Y N S O D I U M 2 %

Eye drops solution

Disodium cromoglycate

Read all of this leaflet carefully before you start using this medicine.
- 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 start to perceive any side effects as serious or if you observe side effects not listed in this Patient Information Leaflet, talk to your doctor or pharmacist.

What is in this leaflet:

1. WHAT CROMOLYN SODIUM 2 % IS AND WHAT IT IS USED FOR

Cromolyn Sodium 2 % is a solution to be administered into the eye. It contains disodium cromoglycate active substance that prevents from the release of substances (histamine and many other substances) responsible for the initiation of an allergic reaction. Cromolyn Sodium 2 % has anti-inflammatory and anti-allergic effects.

Cromolyn Sodium 2 % is used for the prevention and therapy of acute (sharp) and chronic allergic inflammation of conjunctiva (i.e. inflammation from hypersensitivity), such as inflammation of conjunctiva in hay fever or spring keratoconjunctivitis (simultaneous inflammation of cornea and conjunctiva). This medicine should be dropped into the eye preventively before the problems appear.

Cromolyn Sodium 2 % eye drops solution may be used by adults, adolescents, and children aged 4 years and older.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CROMOLYN SODIUM 2 %

Do not use Cromolyn Sodium 2 %
- if you are allergic (hypersensitive) to disodium cromoglycate or to any of the other ingredients of this medicine
- in first three months of pregnancy
- this medicine should not be given to children younger than 4 years

Take special care with Cromolyn Sodium 2 %
- in the second and the third trimesters of pregnancy and during the breastfeeding period (see chapter 'Pregnancy and breastfeeding')

Other medicines and Cromolyn Sodium 2 %
No interactions with other medicines are currently known. However, effects of Cromolyn Sodium 2 % and effects of other medicines may interfere.

Tell your doctor or pharmacist if you are using or have recently used any other over-the-counter medicines.
If a different doctor intends to prescribe a new medicine for you, tell them you are using Cromolyn Sodium 2 % eye drops solution.
If you also use other ocular medications, consult the appropriateness of their concurrent use with the ophthalmologist. It is generally recommended to make at least a five-minute interval between the use of Cromolyn Sodium 2 % and other medicines.

Cromolyn Sodium 2 % with food and drink
As this medicine is an eye drops solution, the use of the medicine has no relation to food and drink.

Pregnancy and breastfeeding
Consult your doctor before you start using any medicine.
This medicine should not be used during first three months of pregnancy. It may be used in the second and third trimesters and during breastfeeding, but only for particularly serious reasons.

Driving and using machines
Shortly after the medicine is dropped into the eye, blurred visions may occur, making thus driving and using machines, or performing other activities that require closer attention, more difficult. It is therefore recommended to perform these activities at least 15 minutes after the medicine is dropped into the eye.

Important information on certain components of Cromolyn Sodium 2 %
This medicine contains a preservative – benzalkonium chloride. Soft contact lenses must not be worn concurrently with the use of Cromolyn Sodium 2 %. Hard contact lenses should be removed from eyes and apply again at least 20 minutes after the medicine is dropped into the eye.

3. HOW TO USE CROMOLYN SODIUM 2 %

Always use Cromolyn Sodium 2 % exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.
Cromolyn Sodium 2 % is normally applied as follows:

Adults and children aged 4 years and older:

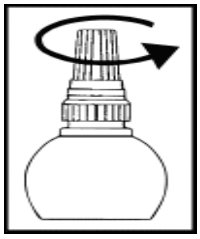
1-2 drops are normally applied into conjunctival sacs of both eyes 3 to 4 times a day in adults and in children aged 4 years and more. It is recommended to maintain regular intervals of at least 4 hours. The therapy should continue also after the acute (severe) problems disappear, for as long as a patient is exposed to an allergen (pollen, dust, fur, etc.).

To achieve the preventive (protective) effect, the therapy should begin 2 or 3 weeks prior to the expected beginning of the allergy season.

Contact lens users
If you use contact lenses, you should remove them before you drop in the Cromolyn Sodium 2 %. After you drop in the Cromolyn Sodium 2 %, wait at least 20 minutes to apply the contact lenses again.

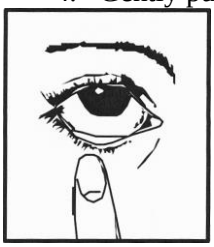
Instructions for application

1. Wash your hands and sit down in a comfortable position or stand.
2. Unscrew the threaded cap.

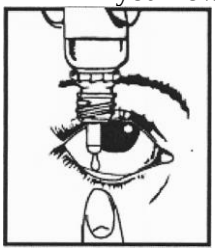


3. Hold the vial downwards, between your thumb and other fingers.

4. Gently pull down the lower eyelid of your affected eye using your index finger.



5. Approach your eye with the dropper tip, not touching your eye or adjacent areas.
6. Gently squeeze the vial, so that only 1 or 2 drops get into your eye and then release your lower eyelid.



7. Using your finger, compress the inner canthus of the affected eye. Hold for a minute with your eye closed.

8. If instructed so by your doctor, repeat the procedure with the second eye.
9. Immediately after the use, apply the cap tightly back onto the vial.

If you use more Cromolyn Sodium 2 % than you should
There is no imminent hazard. At the following application, apply the number of drops as prescribed by the doctor.

In case of accidental use of the medicine by a child, consult the doctor.

If you forget to use Cromolyn Sodium 2 %
Start using this medicine as soon as you realise the omission. Continue with the prescribed dosage at usual times. Do not use a double dose to compensate the omitted dose.

If you stop using Cromolyn Sodium 2 %
Do not stop using Cromolyn Sodium 2 %, unless your doctor instructs you to do so.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cromolyn Sodium 2 % can cause side effects, although not everybody gets them.

Very rare symptoms, occurring immediately after the drops are applied, include burning eyes, conjunctival congestion, sharp pain in the eyes, or a feeling of a foreign object in the eye. These effects are temporary and usually disappear within few minutes.

If you begin to perceive any side effect as serious, or if you observe side effects other than listed in the Patient Information Leaflet, tell it to your doctor.

5. HOW TO STORE CROMOLYN SODIUM 2 %

Store Cromolyn Sodium 2 % medicinal product below 25 °C.
Do not refrigerate or freeze. Protect from light.
Keep out of the reach and sight of children.

Do not use Cromolyn Sodium 2 % after the expiry date printed on the label or the carton under the EXP abbreviation. The expiry date refers to the last day of the month.

Do not use Cromolyn Sodium 2 %, if you notice visible signs of damage to medicine or to a safety band when you first open the vial. In such case, return the medicine back to a pharmacy.

After the first opening, use within 28 days.

Medicinal products must not be disposed of through waste water or household refuse. Unused medicine should be returned to the pharmacy. These measures will help protect the environment.

6. OTHER INFORMATION

What Cromolyn Sodium 2 % contains

- The active substance is disodium cromoglycate 20 mg in 1 ml of the solution.
  The other ingredients are: sodium chloride, disodium edetate dihydrate, benzalkonium chloride (conservation ingredient), water for injection

What Cromolyn Sodium 2 % looks like and contents of the pack

1 × 10 ml, 3 × 5 ml (polyethylene vial with a dropper)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UNIMED PHARMA spol. s r.o., Oriešková 11, 821 05 Bratislava, Slovak Republic

This Patient Information Leaflet was last revised in June 2010.