

SODIUM CROMOGLICATE 2% W/V EYE DROPS

Sodium Cromoglicate 2% w/v

Please read this leaflet carefully before you start to take your medicine. Keep this leaflet. You may need to read it again. If you have any further questions, please ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This medicine will be called Sodium Cromoglicate in this leaflet:

- 1. What Sodium Cromoglicate is and what is it used for**
- 2. Before you use Sodium Cromoglicate**
- 3. How to use Sodium Cromoglicate**
- 4. Possible side effects**
- 5. How to store Sodium Cromoglicate**
- 6. Further information**

1. WHAT SODIUM CROMOGLICATE IS AND WHAT IS IT USED FOR

The active ingredient Sodium Cromoglicate belongs to a group of medicines called anti-inflammatory/anti-allergy agents. Sodium Cromoglicate Eye Drops are used to treat red, watery, itchy eyes caused by allergies such as hayfever, house dust mites and pet hair.

2. BEFORE YOU USE SODIUM CROMOGLICATE

Do not use if you:

- are allergic (hypersensitive) to Sodium Cromoglicate or to any other ingredient of this medicine (see section 6. for more details)

Take special care with Sodium Cromoglicate

Please tell your doctor if you:

- develop an eye infection during this treatment
- are wearing contact lenses.

Taking other medicines

Please tell your doctor or pharmacist if you are applying any other type of eye drops or eye ointment before you start to use this medicine. Your medicine may affect their action and could alter their effect.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without any prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines. Sodium Cromoglicate should not be used during pregnancy and breast-feeding unless considered essential by your doctor.

Driving and using machines

No effects on ability to drive and use machines have been reported. However do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.

Important information about some of the ingredients of Sodium Cromoglicate Eye Drops:

The eye drops contain benzalkonium chloride as preservative which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses before using the eye drops and wait at least 15 minutes before reinserting. The preservative is known to discolour soft contact lenses.

3. HOW TO USE SODIUM CROMOGLICATE

Always use Sodium Cromoglicate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one or two drops in each eye four times daily or as directed by your doctor.

If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

If your symptoms do not improve within 2 days, or if you need to use these drops for more than 3 months, you should consult your doctor.

Instructions for use:

(please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling

- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

Be careful not to touch the tip of the bottle on your eye or on any other surface. Ocular solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

If you use more Sodium Cromoglicate than you should

If you accidentally use too much, **contact your doctor or go to the nearest hospital casualty department immediately.**

If you forget to use Sodium Cromoglicate

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sodium Cromoglicate can cause side effects, although not everybody gets them. If you experience a rare (these may affect between 1 in 1,000 and 1 in 10,000 patients) but serious allergic reaction (difficulty breathing, closing of the throat, swelling of the lips, tongue, or face or hives) to Sodium Cromoglicate **stop using the medication and contact your doctor immediately.**

Please **tell your doctor** if you notice any of the following side effects:

- stinging, burning
- eye irritation,
- blurring of vision

Some people find that their eyes sting or their sight is blurred immediately after using the drops. These effects should wear off after a short time.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SODIUM CROMOGLICATE

Keep all medicines out of the sight and reach of children.

Do not store at a temperature above 30°C.

Protect from direct sunlight

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use Sodium Cromoglicate after the expiry date which is stated on the bottle and on the carton the bottle is packed in.

6. FURTHER INFORMATION

What Sodium Cromoglicate contains

The active ingredient is Sodium Cromoglicate 2% w/v. The eye drops also contain benzalkonium chloride (as preservative) 0.01% w/v, sodium chloride, disodium edetate, polysorbate 80 and water for injections.

What Sodium Cromoglicate look like and contents of the pack

Each bottle contains 5 ml, 10ml or 13.5ml of Sodium Cromoglicate Eye Drops. Your medicine is a clear colourless, sterile solution.

Marketing Authorisation Holder and Manufacturer

FDC International Ltd, Unit 6, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, PO15 7FE

PL numbers: 15872/0010 (13.5ml) 15872/0008 (5ml or 10ml)

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MODE OF USE



(1)
Tighten the cap on the nozzle till the cap touches the shoulder.



(2)
The spike in the cap will pierce the tip of the bottle.



(3)
Tilt head backwards. Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.