

## Package leaflet: Information for the user

### Sodium Cromoglicate 2% w/v Eye drops, solution Sodium cromoglicate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Sodium Cromoglicate 2% w/v Eye drops, solution will be called Sodium Cromoglicate Eye drops.

#### **What is in this leaflet**

1. What Sodium Cromoglicate Eye drops is and what it is used for
2. What you need to know before you use Sodium Cromoglicate Eye drops
3. How to use Sodium Cromoglicate Eye drops
4. Possible side effects
5. How to store Sodium Cromoglicate Eye drops
6. Contents of the pack and other information

#### **1. What Sodium Cromoglicate Eye drops is and what it is used for**

Sodium Cromoglicate Eye drops contains a medicine called sodium cromoglicate. This belongs to a group of medicines called antiallergics.

It works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids.

Sodium Cromoglicate Eye drops are used for the prevention, relief and treatment of eye allergies. This includes:

- Short and long term allergic conjunctivitis (inflammation of parts of the eye)
- More severe cases of conjunctivitis ('vernal kerato conjunctivitis'). Signs include bumps inside the upper eyelid, sensitivity to light and severe itching.

#### **2. What you need to know before you use Sodium Cromoglicate Eye drops**

##### **Do not use Sodium Cromoglicate Eye drops:**

If you are allergic to sodium cromoglicate, or any of the other ingredients of this medicine (listed in section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, tongue and worsening of redness, itching or swelling of the eye or eyelid.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Sodium Cromoglicate Eye drops.

## Warnings and precautions

Take special care with Sodium Cromoglicate Eye drops if you wear soft contact lenses. You should not wear contact lenses while using these drops.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Sodium Cromoglicate Eye drops.

## Other medicines and Sodium Cromoglicate Eye drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any medicine.

## Driving and using machines

You may have blurred eyesight straight after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.

## Sodium Cromoglicate Eye drops contain benzalkonium chloride.

This medicine contains 0.1 mg benzalkonium chloride in each 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.

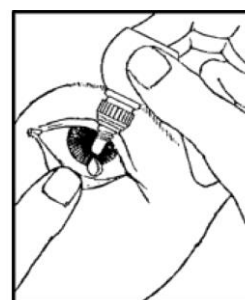
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

## 3. How to use Sodium Cromoglicate Eye drops

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### How to use this medicine

- Wash your hands.
- Before using the medication for the first time, be sure that the tamper-proof seal on the bottle neck is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.
- Remove the cap from the bottle.
- Tilt your head back.
- Squeeze one or two drops inside the lower lid without touching your eye.
- Close your eye.
- Wipe away any excess liquid from the eyes with a clean tissue.
- Always put the cap back on the bottle as soon as you have used it.



- Repeat in the other eye if needed.

### **How much to use (adults, elderly and children)**

- One or two drops in each eye four times a day, or as directed by your doctor.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

### **If you use more Sodium Cromoglicate Eye drops than you should**

Talk to your doctor or go to a hospital straight away.

Remember to take any medicine that is left with you so the doctor knows what you have taken.

### **If you forget to use Sodium Cromoglicate Eye drops**

If you forget a dose, use your drops as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

### **If you stop using Sodium Cromoglicate Eye drops**

Keep using the eye drops until your doctor tells you to stop. Do not stop using the eye drops just because your eyes feel better.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Stop using Sodium Cromoglicate Eye drops and see a doctor as soon as possible if:**

- The itching, redness or swelling gets worse. You may be allergic to these drops.

**Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:**

- Stinging or burning in your eyes or blurring of eyesight. This should only last for a short time and occurs immediately after using the eye drops
- Mild eye irritation

### **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](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Sodium Cromoglicate Eye drops**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton label after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original package in order to protect from light.

Do not use the eye drops more than four weeks after first opening the bottle.

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.

## **6. Contents of the pack and other information**

### **What Sodium Cromoglicate Eye drops contain**

- The active substance is sodium cromoglicate. Each ml of eye drops solution contains 20 mg of sodium cromoglicate.
- The other ingredients are: benzalkonium chloride, disodium edetate and water for injections. See section 2, "Sodium Cromoglicate Eye drops contain benzalkonium chloride".

### **What Sodium Cromoglicate Eye drops look like and contents of the pack**

Sodium Cromoglicate Eye drops is a sterile, clear, colourless to pale yellow solution. It is supplied in plastic bottle with a nozzle and tamper evident plastic screw cap. Each bottle contains 10 ml or 13.5 ml of this medicine.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Neon Healthcare Ltd.  
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#### **Manufacturer**

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