

Patient Information Leaflet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

CROMOSTIL EYE DROPS

(Sodium Cromoglicate 2 % w/v)

Read all of this leaflet carefully because it contains important information for you

CROMOSTIL EYE DROPS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use CROMOSTIL EYE DROPS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CROMOSTIL EYE DROPS with any other person
- Ask your health care provider or pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 2 days.

What is in this leaflet:

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

1. What CROMOSTIL EYE DROPS is and what it is used for

CROMOSTIL EYE DROPS 2 % w/v contains a medicine called sodium cromoglicate which belongs to a group of medicines called anti-allergics. 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.

CROMOSTIL EYE DROPS is used for the treatment of allergic conjunctivitis (red, sore, itchy, and watery eyes).

2. What you need to know before you use CROMOSTIL EYE DROPS

Applicant: FDC SA (Pty) Ltd

Product Name: CROMOSTIL EYE DROPS (Sodium Cromoglicate 2 % w/v)

Approval Date: 12.06.2023

Dosage form and strength: Ophthalmic solution, 2 % w/v

Do not use CROMOSTIL EYE DROPS:

If you are hypersensitive (allergic) to sodium cromoglicate, or any of the other ingredients of CROMOSTIL EYE DROPS (listed in Section 6)

Warnings and precautions

Take special care with CROMOSTIL EYE DROPS

- If you wear soft contact lenses. You should not wear contact lenses while using these drops
- If you suffer from dry eyes

Other medicines and CROMOSTIL EYE DROPS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, breast feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using this 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.

CROMOSTIL EYE DROPS contains Benzalkonium Chloride

This medicine contains benzalkonium chloride. Benzalkonium chloride is a preservative which 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 CROMOSTIL EYE DROPS

Do not share medicines prescribed for you with any other person.

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

How to use this medicine

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- Wash your hands
- 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
- Repeat in the other eye if needed
- Always put the cap back on the bottle as soon as you have used it

How much to use

- One or two drops in each eye four times a day, or as directed by your doctor
- If your symptoms worsen or do not improve, talk to your doctor or pharmacist

Your doctor will tell you how long your treatment with CROMOSTIL EYE DROPS will last. You should not use CROMOSTIL EYE DROPS for longer than absolutely necessary.

If you use more CROMOSTIL EYE DROPS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use CROMOSTIL EYE DROPS

Do not use a double dose to make up for forgotten individual doses.

If you stop using CROMOSTIL EYE DROPS

Even if your symptoms have got better, you should keep using these drops if you are still around the things that you are allergic to. CROMOSTIL EYE DROPS can prevent you getting an allergic reaction so if you stop using it, your allergy symptoms may come back.

4. Possible side effects

CROMOSTIL EYE DROPS can have side effects.

Not all side effects reported for CROMOSTIL EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CROMOSTIL EYE DROPS, please consult your doctor, pharmacist or other healthcare professional for advice.

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If any of the following happens, stop using CROMOSTIL EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital

Frequent side effects:

- Abnormal sensation
- Stinging or burning in the eyes
- Blurring of eyesight

Less Frequency side effects:

- Inflammation within the eye
- Swelling of eyelids
- Wound formation in the eyes.
- Itching
- Foreign body sensation in the eyes
- Round collection of lymphocytes in the eyes

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug reaction Reporting Form" found online under SAHPRA's publications:

<https://www.sahpra.org.za/publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CROMOSTIL EYE DROPS.

5. How to store CROMOSTIL EYE DROPS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30 °C.
- Protect from light.
- Keep the container tightly closed
- Use CROMOSTIL EYE DROPS within 28 days after first opening the bottle.
- Do not use after the expiry date which is stated on the carton and the bottle.

Do not dispose of unused medicines in drains or sewerage systems (e.g. Toilets)

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6. Contents of the pack and other information

What CROMOSTIL EYE DROPS 10 mL & 13,5 mL contains

The active substance is Sodium Cromoglicate.

It also contains Disodium Edetate 0,1% w/v

Sodium chloride.

Benzalkonium chloride.

Polysorbate 80.

Water for injection.

What CROMOSTIL EYE DROPS looks like and contents of the pack.

A clear colourless solution is filled in 10mL clear translucent LDPE vial with white HIPS spike cap and

13,5mL solution filled in 15mL clear translucent LDPE vial with white HIPS spike cap.

One such vial is packed in a printed carton with Package insert.

HOLDER OF THE CERTIFICATE OF REGISTRATION

FDC SA (Pty) Limited

Unit J3, The Willows Office Park,

Farm Road, The willows, Pretoria East,

Pretoria, 0081,

South Africa

This leaflet was last revised in: 12 June 2023

REGISTRATION NUMBER : 47/15.4/0671

Access to the corresponding Professional Information

Scan the QR code to access the corresponding professional Information (PI) and HCR details

