

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

STOP-ALLERG EYE DROPS

2,0 % w/v Eye drop, solution

Sodium cromoglycate 20 mg/ml

Preservative: Benzalkonium chloride solution 0,01 % m/v

Read all of this leaflet carefully before you start taking STOP-ALLERG EYE DROPS

STOP-ALLERG EYE DROPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use STOP-ALLERG EYE DROPS carefully to get the best results from it.

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

What is in this leaflet

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

1. What STOP-ALLERG EYE DROPS is and what it is used for

STOP-ALLERG EYE DROPS contains sodium cromoglycate as an active substance. It belongs to a group of medicines called anti-allergens. STOP-ALLERG EYE DROPS is used to treat and relieve these signs of eye allergies.

2. What you need to know before you take STOP-ALLERG EYE DROPS

Do not take STOP-ALLERG EYE DROPS:

- If you are hypersensitive to sodium cromoglycate or any of the other ingredients of STOP-ALLERG EYE DROPS.

Warnings and precautions

Special care should be taken with STOP-ALLERG EYE DROPS:

- If given concomitantly with steroid treatment and sodium cromoglycate is withdrawn
- Please consult your doctor if used for a long period of time
- Patients should seek advice before they discontinue use of STOP-ALLERG EYE DROPS.

Other medicines and STOP-ALLERG EYE DROPS

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

No interactions known.

Pregnancy, breastfeeding and fertility

Safety in pregnancy, lactation and fertility has not been established.

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 health care provider for advice before taking this medicine.

Driving and using machinery

Transient stinging, burning or blurred vision may occur after instillation of STOP-ALLERG Eye drops.

Do not drive or operate machinery until proper vision is restored.

It is not always possible to predict to what extent STOP-ALLERG EYE DROPS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STOP-ALLERG EYE DROPS affects them.

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STOP-ALLERG EYE DROPS contains benzalkonium chloride

This medicine contains 0,24 mg benzalkonium chloride 50 % solution in 1 litre which is equivalent to 0,01 % m/v.

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 an abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to take STOP-ALLERG EYE DROPS

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

Always take STOP-ALLERG EYE DROPS exactly as described in this leaflet or as your doctor, pharmacist, or nurse if you are not sure.

The usual dose:

For adults (including the elderly) and children: 1-2 drops into each eye 4 times daily.

STOP-ALLERG EYE DROPS should be used regularly to ensure optimal control of symptoms.

It is recommended that treatment is continued during the period to the allergen, even when free of symptoms.

For ophthalmic use only

Care should be taken to avoid contamination of the contents during use.

Patient should be advised not to wear soft contact lenses during treatment with STOP-ALLERG EYE DROPS.

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How to apply your eye drops:

1. Wash your hands before using STOP-ALLERG EYE DROPS.
2. You may want to sit in front of a mirror to see what you are doing. Tilt your head backwards, gently pull down your lower eyelid and carefully place 1-2 drops into the space of your eyelid and the eye. Ensure you do not touch the dropper with your eye or fingers.
3. Release the eyelid and blink a few times to ensure the liquid covers the surface of the eye.
4. Repeat the procedure on the other eye and close the bottle with the cap.
5. Wash hands after application of STOP-ALLERG EYE DROPS.

If you use more STOP-ALLERG EYE DROPS than you should

In the event of an overdose, or if someone has accidentally swallowed STOP-ALLERG EYE DROPS, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take STOP-ALLERG EYE DROPS

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible Side Effects

STOP-ALLERG EYE DROPS can have side effects.

Not all side effects reported for STOP-ALLERG EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STOP-ALLERG EYE DROPS, please consult your health care provider for advice.

If any of the following happens, stop taking / using STOP-ALLERG EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

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These are all very serious side effects. If you have them, you may have had a serious reaction to STOP-ALLERG EYE DROPS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects:

Less Frequent Side effects:

- Local irritation

Unknown side effects:

- Hypersensitivity reactions (including headache, skin rash, difficulty breathing, breathlessness, anaphylaxis).
- Transient burning or stinging and blurring may occur after instillation, other symptoms of local irritation have been reported rarely.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of STOP-ALLERG EYE DROPS.

You may also report to Adcock Ingram Limited using the following email:
Adcock.AEReports@adcock.com

5. How to store STOP-ALLERG EYE DROPS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Do not use after the expiry date stated on the label / carton / bottle.

Discard 30 days after opening.

Return all unused medicine to your pharmacist.

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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STOP-ALLERG EYE DROPS contains

The active substance is sodium cromoglycate 20 % w/v (20,0 mg per 1 ml).

The preservative is benzalkonium chloride 0,01 % w/v.

The other ingredients are disodium edetate and purified water.

What STOP-ALLERG EYE DROPS looks like and contents of the pack

STOP-ALLERG EYE DROPS is a clear colourless to clear yellow liquid.

The primary packaging is a white bottle with tips and caps tamper proof screw of 10 ml and 15 ml.

Holder of Certificate of Registration

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