PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

STOP-ALLERG EYE DROPS

2,0 % $^{w}/_{v}$ Eye drop, solution

Sodium cromoglycate 20 mg/ml

Read all of this leaflet carefully before you start using 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 use STOP-ALLERG EYE DROPS
3. How to use 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-allergenics. STOP-ALLERG EYE DROPS is used to treat and relieve the signs of eye allergies.

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

Do not use STOP-ALLERG EYE DROPS:

- If you are hypersensitive to sodium cromoglycate or any of the other ingredients of STOP-ALLERG EYE DROPS as listed in section 6.

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- If given concomitantly with steroid treatment and sodium cromoglycate is withdrawn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 healthcare 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.

STOP-ALLERG EYE DROPS contains benzalkonium chloride

This medicine contains 0,24 g 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 use STOP-ALLERG EYE DROPS

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

Always use STOP-ALLERG EYE DROPS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with 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 of exposure 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.

How to use the 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 between 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 use of STOP-ALLERG EYE DROPS.

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

In the event of an overdosage, 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 use 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 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

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 frequent 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 direct 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.

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 2,0 % w/v (20,0 mg per 1 ml).

The preservative is benzalkonium chloride 0,01 % m/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.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK /232625

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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S2

STOP-ALLERG EYE DROPS

2,0 % *m/v*, Oogdruppel, oplossing

Natriumkromoglikaat 20 mg/ml

Lees hierdie hele biljet noukeurig deur voordat u STOP-ALLERG EYE DROPS begin gebruik

STOP-ALLERG EYE DROPS is beskikbaar sonder 'n doktersvoorskrif, vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds STOP-ALLERG EYE DROPS versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie STOP-ALLERG EYE DROPS met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat is in hierdie biljet

1. Wat STOP-ALLERG EYE DROPS is en waarvoor dit gebruik word
2. Wat u moet weet voordat u STOP-ALLERG EYE DROPS gebruik
3. Hoe om STOP-ALLERG EYE DROPS te gebruik
4. Moontlike newe-effekte
5. Hoe om STOP-ALLERG EYE DROPS te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat STOP-ALLERG EYE DROPS is en waarvoor dit gebruik word

STOP-ALLERG EYE DROPS bevat natriumkromoglikaat as 'n aktiewe bestanddeel. Dit behoort tot 'n groep medisyne wat anti-allergie middels genoem word. STOP-ALLERG EYE DROPS word gebruik om die tekens van oogallergieë te behandel en te verlig.

2. Wat u moet weet voordat u STOP-ALLERG EYE DROPS gebruik

Moenie STOP-ALLERG EYE DROPS gebruik nie:

- Indien u hipersensitief is vir natriumkromoglikaat of enige van die ander bestanddele van STOP-

ALLERG EYE DROPS soos gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet gedra word met STOP-ALLERG EYE DROPS:

- Indien dit gelyktydig met steroïed-behandeling gegee word en natriumkromoglikaat word onttrek
- Raadpleeg asseblief u dokter indien dit vir 'n lang tydperk gebruik word
- Pasiënte moet advies inwin voordat hulle die gebruik van STOP-ALLERG EYE DROPS staak.

Ander medisyne en STOP-ALLERG EYE DROPS

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Geen interaksies is bekend nie.

Swangerskap, borsvoeding en vrugbaarheid

Veiligheid tydens swangerskap, laktasie en vrugbaarheid is nie vasgestel nie.

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjinerie

Verbygaande steekgevoel, brandgevoel of versteurde visie kan voorkom na toediening van STOP-ALLERG EYE DROPS. Moenie bestuur of masjinerie gebruik voordat die behoorlike sig herstel is nie. Dit is nie altyd moontlik om te voorspel in watter mate STOP-ALLERG EYE DROPS die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe STOP-ALLERG EYE DROPS hulle beïnvloed nie.

STOP-ALLERG EYE DROPS bevat bensalkoniumchloried

Hierdie medisyne bevat 0,24 g bensalkoniumchloried 50 % oplossing in 1 liter wat gelykstaande is aan 0,01 % *m/v*.

Bensalkoniumchloried kan deur sagte kontaklense geabsorbeer word en kan die kleur van die kontaklense verander. U moet kontaklense verwyder voordat u hierdie medisyne gebruik en dit 15 minute na gebruik terugsit.

Bensalkoniumchloried kan ook oogirritasie veroorsaak, veral indien u droë oë of afwykings van die kornea (die deursigtige laag aan die voorkant van die oog) het. Indien u 'n abnormale oogsensasie, steekgevoel of pyn in die oog voel nadat u hierdie medisyne gebruik het, raadpleeg u dokter.

3. Hoe om STOP-ALLERG EYE DROPS te gebruik

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Gebruik altyd STOP-ALLERG EYE DROPS presies soos beskryf in hierdie biljet of soos u dokter, apteker of verpleegkundige u ingelig het. Raadpleeg u dokter, apteker of verpleegkundige indien u nie seker is nie.

Die algmene dosis:

Vir volwassenes (insluitend bejaardes) en kinders: 1-2 druppels in elke oog 4 keer per dag.

STOP-ALLERG EYE DROPS moet gereeld gebruik word om optimale beheer van simptome te verseker.

Dit word aanbeveel dat behandeling voortgesit word gedurende die tydperk van blootstelling aan die allergeen, selfs wanneer simptoom-vry.

Slegs vir oftalmiese gebruik

Sorg moet gedra word om besoedeling van die inhoud tydens gebruik te voorkom.

Pasiënt moet aangeraai word om nie sagte kontaklense te dra tydens behandeling met STOP-ALLERG EYE DROPS nie.

Hoe om die oogdruppels te gebruik:

1. Was u hande voordat u STOP-ALLERG EYE DROPS gebruik.
2. U sal dalk voor 'n spieël wil sit om te sien wat u doen. Kantel u kop agtertoe, trek u onderste ooglid saggies af en plaas 1-2 druppels versigtig in die spasie tussen u ooglid en die oog. Maak seker dat u nie aan die drupper met u oog of vingers raak nie.
3. Laat die ooglid los en knip 'n paar keer om te verseker dat die vloeistof die oppervlak van die oog bedek.

4. Herhaal die prosedure met die ander oog en maak die bottel toe met die doppie.
5. Was hande na gebruik van STOP-ALLERG EYE DROPS.

Indien u meer STOP-ALLERG EYE DROPS gebruik as wat u moes

In die geval van 'n oordosis, of indien iemand per ongeluk STOP-ALLERG EYE DROPS gesluk het, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om STOP-ALLERG EYE DROPS te gebruik

Moenie 'n dubbele dosis neem/ontvang om vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

STOP-ALLERG EYE DROPS kan newe-effekte hê.

Nie alle newe-effekte wat vir STOP-ALLERG EYE DROPS aangemeld is, word by hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u STOP-ALLERG EYE DROPS neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om STOP-ALLERG EYE DROPS te gebruik en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- veluitslag of jeukerigheid

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op STOP-ALLERG EYE DROPS gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter in indien u enige van die volgende newe-effekte opmerk:

Minder gereelde newe-effekte:

- Plaaslike irritasie

Newe-effekte met onbekende frekwensie:

- Hipersensitiwiteitsreaksies (insluitend hoofpyn, veluitslag, asemhalingsprobleme, asemloosheid, anafilakse).
- Verbygaande brand- of steekgevoel en vervaagde visie kan voorkom na toediening; ander simptome van plaaslike irritasie is selde aangemeld.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van STOP-ALLERG EYE DROPS. U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com

5. Hoe om STOP-ALLERG EYE DROPS te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 25 °C.

Beskerm teen direkte lig.

Moenie gebruik ná die vervaldatum wat op die etiket/kartonboksie/bottel vermeld word nie.

Gooi weg 30 dae ná oopmaak is.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat STOP-ALLERG EYE DROPS bevat

Die aktiewe bestanddeel is natriumkromoglikaat 2,0 % *m/v* (20,0 mg per 1 ml).

Die preserveermiddel is bensalkoniumchloried 0,01 % *m/v*.

Die ander bestanddele is dinatriumedetaat en gesuiwerde water.

Hoe STOP-ALLERG EYE DROPS lyk en die inhoud van die verpakking

STOP-ALLERG EYE DROPS is 'n deursigtige, kleurlose tot deursigtige, geel vloeistof.

Die primêre verpakking is 'n wit bottel met punte en doppies met peuter-bestande skroef van 10 ml en 15 ml.

Nie alle verpakkingsgroottes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie

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Kliëntediens: 0860 ADCOCK /232625

Hierdie biljet is mees onlangs hersien op

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Registrasienommer

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