Allergo-COMOD® eye drops 20 mg/ml eye drops

Active substance: Sodium cromoglicate (Ph. Eur.)

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However you still need to use Allergo-COMOD® eye drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after some days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Allergo-COMOD® eye drops are and what they are used for

Allergo-COMOD® eye drops are eye drops for the treatment of allergic conjunctivitis.

Allergo-COMOD® eye drops are indicated for the treatment of acute and chronic allergic conjunctivitis, for instance hay fever or vernal kerato-conjunctivitis.

2. Before you use Allergo-COMOD® eye drops

Do not use Allergo-COMOD® eye drops
- if you are hypersensitive against sodium cromoglicate (Ph. Eur.) or one of the other ingredients.

Take special care with Allergo-COMOD® eye drops
- when you wear contact lenses. In principle contact lenses must not be worn in allergic conjunctivitis. If the ophthalmologist in exceptional cases allows to wear contact lenses the following has to be considered: Remove contact lenses before application of the eye drops and reinsert them 15 minutes after application of the eye drops.

Using other medicines
Interactions are not known.
Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without prescription.
Advice:
If you use any other eye drops or eye ointment there should be an interval of 15 minutes between the applications. Eye ointments should always been applied at last.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacists for advice before using any medicine.

No teratogenic effect was observed in men by now, but the existing experience is not sufficient for a final benefit-risk-assessment. The active substance is secreted in small amounts into breast milk.

Therefore, Allergo-COMOD® eye drops should be used in the first trimenon of pregnancy for safety reasons only after a careful benefit-risk-assessment. Also in the further course of pregnancy and lactation Allergo-COMOD® eye drops should only be used after a benefit-risk-assessment of the treating doctor.

**Driving and using machines**

Immediately after applying Allergo-COMOD® eye drops vision will be blurred for a short time. You cannot react quickly and well-targeted enough on unexpected and sudden events. Wait some minutes after the application of the eye drops before driving, operating electric tools or machinery or work without stable footing.

**3. How to use Allergo-COMOD® eye drops**

Always use Allergo-COMOD® eye drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The following instructions are valid as far as your ophthalmologist did not give you any different recommendations. Please follow the instructions, because otherwise Allergo-COMOD® eye drops cannot work properly.

The usual dose is: Adults and children instill one drop in the diseased eye four times a day.

The daily dose may be increased in frequency to 6 times daily one drop or also doubled to 8 times daily one drop.

Remove the cap before use. Before the first application please turn the bottle of the Allergo-COMOD® eye drops with its tip down and press onto the bottom of the bottle until the first drop appears at the nozzle. Now the bottle is ready for further use. Hold the bottle upside down and apply a strong and quick pressure on the bottom of the bottle. This activates the mechanism for the release of one drop. Because of the special COMOD® valve system, size and speed of each drop are the same however much pressure is applied. Lean your head back slightly, pull down your lower eyelid and instil one drop into the lower eye. Slowly close your eye to allow the fluid to spread evenly on the eye’s surface. Replace cap immediately after using. Please take care that the dropper tip is dry. When applying the fluid, please avoid any contact between the tip of the bottle and your eye or your skin.

You should continue the treatment with Allergo-COMOD® eye drops as long as you stay in contact with the allergen(s) (e.g. pollen, house dust, mould spores).
If you want to use Allergo-COMOD® eye drops over a longer period of time, you should ask your ophthalmologist about the necessity of the treatment.

Please talk to your doctor if you have the impression that the efficacy of Allergo-COMOD® eye drops is too strong or too weak.

**If you used more of Allergo-COMOD® eye drops than you should**, no particular action has to be taken. No cases of overdose became known by now. If a child may have swallowed the solution, there is no danger of intoxication.

**If you forgot to use Allergo-COMOD® eye drops**, do not use a double dose. Make up for the forgotten dose as soon as possible and apply afterwards the same amount and in the same frequency as described above or prescribed by your doctor.

If you have further questions on the use of this product please ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, Allergo-COMOD® eye drops can cause side effects, although not everybody gets them.

For the assessment of side effects the following frequencies of occurrence are defined:

- **Very common:** more than 1 of 10 treated patients
- **Common:** 1 to 10 of 100 treated patients
- **Uncommon:** 1 to 10 of 1000 treated patients
- **Rare:** 1 to 10 of 10 000 treated patients
- **Very rare:** less than 1 of 10 000 treated patients
- **Not known:** frequency on basis of the available data not assessable

In rare cases burning, foreign-body-sensation, swelling of the conjunctiva (chemosis) and increased blood flow in the conjunctiva (conjunctival hyperaemia) may occur. Usually the complaints recover spontaneously. In case of more severe disorders, especially in suspicion of a hypersensitivity against Allergo-COMOD® eye drops, please consult your ophthalmologist.

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 your pharmacist.

### 5. How to store Allergo-COMOD® eye drops

Keep Allergo-COMOD® eye drops out of the reach and sight of children!

Do not use Allergo-COMOD® eye drops after the expiry date which is stated on the carton and the bottle.

Keep the container in the outer carton to protect the content from sunlight.

Do not store above 25°C.

With proper care Allergo-COMOD® eye drops can be used up to 12 weeks after first opening.
6. Further information

**What Allergo-COMOD® eye drops contains**
The active substance is sodium cromoglicate (Ph.Eur.) 20 mg/ml. The other ingredients are sodium edetate (Ph.Eur.), sorbitol, water for injections.

Allergo-COMOD® eye drops do not contain any preservatives.

**What Allergo-COMOD® eye drops look like and contents of the pack**
Allergo-COMOD® eye drops are clear, colourless to slightly yellow eye drops filled into a multidose-container with gas-free pump system of 10 ml.
Each pack contains one or two dropper bottles.

**Marketing authorisation holder and manufacturer**

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**Further pharmaceutical forms:**

*Allergocrom® Nasal Spray 15 ml solution (preservative-free)*
*Allergo-COMOD® Nasal Spray 15 ml solution (preservative-free)*
*Allergo-COMOD® Combipack with 10 ml eye drops and 15 ml nasal spray solution (preservative-free)*

**Dear patient!**

*For the therapy of allergic conjunctivitis, the tolerance of eye drops is very important. Allergo-COMOD® eye drops is a highly effective and very good tolerable medicinal product, which does not contain any preservatives. Therefore an undesirable effect on the superficial tissues of the eye like conjunctiva and cornea and an additional and needless risk of allergy caused by a preservative does not exist.*

*With the COMOD®-system, the first innovative application system for preservative-free eye drops as a multi-dose container is available. This enormous improvement in medicinal eye therapy is realised by the use of a solely mechanical running pump-mechanism. Therefore, it must be pressed on the bottom of the bottle to take out a drop in contrast to conventional eye drop containers.*

*The treatment of an allergic conjunctivitis is a long-term therapy that should not be interrupted. Write the date of first use on the bottle or on the folding carton. Because one*
bottle of Allergo-COMOD® eye drops is sufficient for about 5 weeks, you will know when you will need a new bottle early enough.

It is guaranteed that out of one bottle of Allergo-COMOD® 10 ml of eye drops can be removed. For production reasons, a small amount of the solution remains in the bottle.

Please avoid the contact of Allergo-COMOD® eye drops with textiles, because the formation of spots after washing cannot be excluded.

Pack size:

10 ml eye drops (N1)
2 x 10 ml eye drops (N2)