

## **Chloramphenicol-POS 1%, eye ointment 10 mg/g**

Active substance: Chloramphenicol

### **What chloramphenicol-pos 1% is and what it is used for**

Chloramphenicol-POS 1%, eye ointment 10 mg/g, is an antibiotic.

Chloramphenicol-POS 1% is used for eye infections caused by chloramphenicol-sensitive bacteria in adults and children.

### **When you should not use this medicine or when you should take extra care with it**

When should you not use this medicine?

- If you are allergic to any of the ingredients in this medicine.
- If you have disorders in the formation and development of blood cells.
- If you have a severe liver function disorder.
- If there is a known family history of a medicine damaging the bone marrow.

### **When should you take extra care with this medicine?**

Contact your doctor or pharmacist before using this medicine.

- Even with ophthalmic use of Chloramphenicol, changes in blood count are possible, but only in very rare cases. Chloramphenicol-POS 1% should therefore not be used for more than 10 days.

If you use Chloramphenicol-POS 1%, you cannot wear contact lenses during treatment.

If long-term treatment (more than 14 days) is necessary, your blood count should be regularly checked due to the risk of bone marrow failure (your body produces too few blood cells).

In case of side effects, such as hypersensitivity reactions, use should be immediately discontinued.

### **Are you taking any other medications?**

Are you currently taking or have you recently taken any other medications, or is there a possibility that you will use other medications in the near future? Tell your doctor or pharmacist about it. This also applies to medications that do not require a prescription.

Chloramphenicol can, even with local application, enhance the effect of other medications that can have a harmful effect on the formation of blood cells.

Therefore, always inform your treating physician of any medications you are taking.

Concomitant use of corticosteroids (hormones formed in the adrenal cortex) can mask the symptoms of an infection.

**Pregnancy and breastfeeding:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor or pharmacist before using this medicine.

**Pregnancy:** Chloramphenicol crosses the placenta (afterbirth) and is excreted in breast milk. It can cause a so-called gray syndrome in the fetus or infant (vomiting, pallor, blue discoloration of the skin and mucous membranes, swollen belly, and circulatory disorders). At a dose of 5 mg per day, the risk is likely not so great that this product needs to be avoided during pregnancy.

**Breastfeeding:** Chloramphenicol crosses the placenta (afterbirth) and is excreted in breast milk. It can cause a so-called gray syndrome in the fetus or infant (vomiting, pallor, blue discoloration of the skin and mucous membranes, swollen belly, and circulatory disorders). At a dose of 5 mg per day, the risk is likely not so great that this product needs to be avoided during breastfeeding.

**Driving and using machinery:** Immediately after administration, vision may be temporarily affected. This is caused by the distribution of the ointment over the cornea of the eye. You should take this into account when participating in traffic and operating machinery.

Chloramphenicol-POS 1% contains wool wax

May cause local skin reactions (e.g. contact dermatitis).

### **How to use this medicine?**

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

You should use this eye ointment as a general supplement to treatment with chloramphenicol eye drops. Before going to bed, apply a 1 cm strip of ointment to the inner side of the lower eyelid. The recommended dosage is to apply a 1 cm strip of ointment to the inner side of the lower eyelid 2-4 times a day. After the infection symptoms have disappeared, treatment should be continued for another 48 hours.

Unscrew the cap of the tube. Tilt your head back and look upward. Pull the lower eyelid forward to create a kind of pocket. Gently squeeze the tube so that 1 cm of ointment gets into the eye. Avoid touching the tube opening to the eye or eyelids as much as possible.

The duration of treatment can vary from a few days to a maximum of 14 days, preferably not longer than 10 days. If you notice that Chlooramfenicol-POS 1% is too strong or too weak, consult your doctor or pharmacist.

Use in children: In newborn babies, a dosage adjustment may be necessary due to reduced systemic elimination caused by an immature metabolism and the risk of dose-dependent side effects. The maximum treatment duration is 10-14 days.

If you have used too much of this medicine, immediately contact your doctor or pharmacist. Do not take a double dose to make up for a missed dose. When using antibiotics, it is important to complete the treatment. If not all bacteria are killed, the symptoms may return.

Possible side effects: Like any medicine, this medicine can have side effects, although not everyone experiences them. Very rarely (occurring in less than 1 in 10,000 users), disturbances in blood formation may occur, even though the doses of chloramphenicol used in the eye are very low:

- Too few white and red blood cells and platelets (pancytopenia)
- Too few white blood cells in your blood (leukopenia).
- Too few white blood cells. This makes you more susceptible to getting sick (agranulocytosis).
- Few platelets in your blood. Platelets help form a scab on a wound.
- Inflammation of the optic nerve (Optic Neuritis) with eye pain and poor vision.
- Unknown (cannot be determined with the available data):
- Allergic reactions (hypersensitivity reactions) are possible, such as itching, burning sensation, swelling of the eyelid, swelling and redness of the conjunctiva.
- You suddenly experience: a swollen tongue, swollen lips, a swollen face, a swollen throat (angioedema).
- Skin rash with pink bumps and severe itching (hives or urticaria).
- Skin rash with red spots.
- Bitter taste.
- Reporting side effects

#### **How to store this medicine?**

- Store below 25 °C.
- Keep out of sight and reach of children.
- Do not use this medicine after the expiry date stated on the label after 'EXP'. The last day of that month is the expiry date.
- After opening the tube, it is usable for 1 month.
- Do not dispose of medicines in the wastewater or garbage can. Ask your pharmacist what to do with medicines that you no longer use. They will be disposed of in a responsible manner and will not harm the environment.