

## CHLORAMPHENICOL KRKA

10 mg / g Eye Ointment

CHLORAMPHENICOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What Chloramphenicol Krka is and what it is used for
2. Before you use Chloramphenicol Krka
3. How to take Chloramphenicol Krka
4. Possible side effects
5. How to store Chloramphenicol Krka
6. Further information

#### 1. WHAT CHLORAMPHENICOL KRKA IS AND WHAT IT IS USED FOR

Chloramphenicol is an antibiotic that destroys bacteria or hindering their growth. ATC code: S01AA01. It is used for the treatment of infections, caused by a number of bacteria. Chloramphenicol ointment Krka is intended for the treatment of:

- Bacterial blepharitis (inflammation of the eyelids)
- Conjunctivitis (inflammation of the joints)
- Keratitis (inflammation of the cornea) and
- Infections that occur after mechanical injury of conjunctiva and cornea.

#### 2. BEFORE YOU USE CHLORAMPHENICOL KRKA

##### **Do not use Chloramphenicol Krka:**

- if you are allergic (hypersensitive) to chloraphenicol or any of the other ingredients of Chloramphenicol Krka
- If you have ever had severe damage of the bone marrow.

### **Take special care with Chloramphenicol Krka**

- If you suspect that your eye condition is worse than at the beginning of treatment, or after a few days
- if there is no improvement, consult a doctor; you may need to replace the drug.
- When using the drug for a long time, can grow bacteria that are resistant to the drug.
- Ointment use only as much time as prescribed by your doctor. Treatment of it must not be too often because even after the topical application of chloramphenicol severe damage to bone marrow function may occur.
- Safety of use in children younger than two years has not been confirmed.
- During treatment with ointments do not wear contact lenses
- Since the ointment can slow down the healing of cornea, we do not recommend it with the ulceration (surface tissue decomposition due to processes on the surface or below it).

### **Using other medicines**

Inform your doctor if you are taking or have recently taken any drug, and if you are acquired these medicines without a prescription.

Simultaneous treatment with penicillin and chloramphenicol reduces their antimicrobial activity. They interact only with systemic administration of chloramphenicol.

Chymotrypsin drops that you get after eye lenses surgery for cataract, will not work if you use an ointment Chloramphenicol Krka simultaneously.

### **Pregnancy and breast-feeding**

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Harmlessness of use of Chloramphenicol Krka ointment during pregnancy has not been confirmed. During pregnancy and lactation you can use the ointment for a very short time and only in certain cases, when the potential benefit justifies the risk.

### **Driving and using machines**

This ointment can transiently reduce visual acuity. Do not operate motor vehicles or machines until your vision is completely clear.

## **3. HOW TO TAKE CHLORAMPHENICOL KRKA**

Always take Chloramphenicol Krka exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Usually, in the first 48 hours apply about 1 cm of ointment in about every 3 to 4 hours. After two days, you can lengthen the distance between the two doses.

Always place the ointment with washed hands. Use your fingers to gently pull the lower eyelid down, with the other hand squeeze the ointment out of the tube to the inside of the lower eyelid. Make sure that the tip of the tube does not touch the eye.

### **If you use more CHLORAMPHENICOL KRKA than you should**

- The possibility to have any difficulties due to the overdose is very small.

### **If you forget to use CHLORAMPHENICOL KRKA**

- Do not take a double dose to make up for a forgotten dose.

### **If you stop using CHLORAMPHENICOL KRKA**

- We recommend you to follow the treatment regimen, and, if necessary, consult your doctor about discontinuation of treatment.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may occur at regular intervals, as defined below:

**Very common:** Occurring in more than 1 in 10 patients

**Common:** Often occur in 1 to 10 in 100 patients

**Less common:** Occur in 1 to 10 in 1,000 patients

**Rare:** Occur in 1 to 10 in 10,000 patients

**Very rare:** Occurring in less than 1 in 10,000 patients

**Occasional:** in some patients hypersensitivity reactions appear in the form of vesicular and maculopapular dermatitis (an allergic skin disease with inflammation and numerous various spots that itch, and bubbles), urticaria (red bordered rash that is very itchy) and angioedema (allergic reaction to the Food and Drug Administration).

**Rare:** at the injection site signs of hypersensitivity reactions such as a burning sensation or itching may occur. If burning or itching does not go away after a few minutes or are very strong and are accompanied by changes in the skin around the eye (itching, redness, swelling), consult a doctor. You could be allergic to the ointment.

**Very rare:** in some cases with the local administration of chloramphenicol signs of toxic effects on bone marrow appear. It can cause a specific type of anemia (aplastic anemia), which can otherwise occur when chloramphenicol is taken orally. In case there are signs of undesirable effects of chloramphenicol, we have to stop the treatment.

If you notice any side effects please tell your doctor or pharmacist.

#### 5. HOW TO STORE CHLORAMPHENICOL KRKA

- Keep this medicine out of the sight and reach of children.
- Do not store above 30 °C. Store in the original carton.
- Do not use Chloramphenicol Krka after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Expiry date: 3 years.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. FURTHER INFORMATION

##### **What Chloramphenicol Krka contains**

The active substance is chloramphenicol. 1 g of eye ointment contains 10 mg of chloramphenicol.

The other ingredients are liquid paraffin and white petrolatum.

##### **What Chloramphenicol Krka looks like and contents of the pack**

The ointment is white to bright yellow in color.

It comes in boxes with a tube that contains 5g of ointment.

##### **The regime of dispensing**

The drug is issued on prescription.

##### **Manufacturer**

Krka Ltd., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia.