

**Package leaflet:  
Information for the user**



**5mg/ml  
Eye Drops, Solution**

Chloramphenicol

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

-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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**Important information about the administration of this product**

Eykappo Eye Drops are contained within a novel multi-dose eye drop bottle, which allows for the solution not to contain any preservatives. Due to the design of the container, administration with these eye drops is not the same as standard eye drop bottles.

- Prior to first use, practice using the drops away from the eye. Slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop.
- Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard, or more than one drop may come out.
- After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.
- If more than one type of eye drop is used, leave at least 5 minutes between administration of each eye drop solution.

Please read the full instructions on the correct use of this product in **Section 3** of the leaflet ("How to use Eykappo"), before using these eye drops.

**What is in this leaflet**

1. What Eykappo is and what it is used for
2. What you need to know before you use Eykappo
3. How to use Eykappo
4. Possible side effects
5. How to store Eykappo
6. Contents of the pack and other information

**1. What Eykappo is and what it is used for**

Eykappo contains a medicine called chloramphenicol. This belongs to a group of medicines called antibiotics. It is used to treat infections of your eyes.

Sometimes parts of the outer surface of the eye, such as the cornea (the transparent membrane covering the surface of the eye) or the conjunctiva (the lining of the inside of the eyelids and part of the eye), may become infected with bacteria. These eye drops can be used to treat this infection and are effective against many different types of bacteria.

If the eye infection is very severe, your doctor may give you antibiotic tablets as well as these antibiotic eye drops.

This medicine is indicated for children, adults and the elderly.

Eykappo eye drops solution is a sterile solution that does not contain a preservative.

**2. What you need to know before you use Eykappo**

**Do not use Eykappo:**

- if you are allergic to chloramphenicol or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor or pharmacist before using Eykappo.

If you use these eye drops over a long period of time they could possibly become less effective or produce allergic reactions. In order to prevent this, make sure that you stop using this medicine as soon as your doctor tells you to.

If you have a history of contact hypersensitivity to silver, you should not use this product.

**Children and adolescents**

Eykappo can be used in children and adolescents.

**Other medicines and Eykappo**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Pregnancy and breast-feeding**

If you are pregnant, may be pregnant or are breast-feeding, tell your doctor or eye specialist. He/she may decide to use these drops or to prescribe you an alternative.

The drops should not be used during pregnancy and breast-feeding unless considered essential by your doctor.

**Contact lenses**

Contact lenses should not be worn in an infected eye. Your doctor will ask you to remove your contact lenses prior to the administration of the drops.

Do not wear your contact lenses throughout the entire treatment course.

**Driving and using machines**

As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

**Eykappo contains boron**

This medicine should not be given to a child younger than 2 years without medical advice, as it contains boron and may impair fertility in the future.

**3. How to use Eykappo**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Do not use this product for longer than the time frame stated by your doctor or eye specialist, as it may become less effective at treating your eye infection.**

**Dose**

The recommended dose is 1 to 2 drops to each infected eye up to six times a day. You should continue your treatment for 2 days after symptoms disappear, to prevent the recurrence of infection. The maximum recommended duration of treatment is 14 days.

**If your eyes get worse** or are not better after a few days of using these eye drops, see your doctor or eye specialist or pharmacist.

**Use in children**

It may be necessary to adjust the dose for newborn infants as, due to their immature metabolism they may be at risk of dose-related adverse effects. The maximum duration of treatment is 10-14 days.

Do not allow the tip of the multi-dose container to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

To avoid possible contamination of the multi-dose container, keep the tip of the multi-dose container away from contact with any surface.

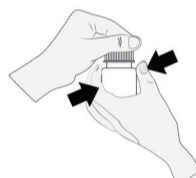
**Instructions for use**

**Before instillation of the eye drops:**

- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should first of all practice using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

**Instillation:**

1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



2. Tilt your head backwards and hold the bottle above your eye.
3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.

If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.



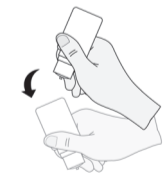
4. Blink a few times so that the drop spreads over the eye.



5. After using Eykappo, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop the solution getting into the rest of your body.



6. Repeat the instructions 2 – 5 to deliver a drop into the other eye also, if your doctor has instructed you to do this. Sometimes only one eye needs to be treated and your doctor will advise if this applies to you and which eye needs treatment.
7. After each use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.



8. After you have used all doses there will be some Eykappo left in the bottle. You should not be concerned since an extra amount of Eykappo has been added and you will get the full amount of Eykappo that your doctor has prescribed. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment. Do not use the eye drops for longer than 28 days after first opening the bottle.

**If you use more Eykappo than you should**

An overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

**If you forget to use Eykappo**

If you forget a dose, use your drops as soon as you remember and then go on as before.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.



#### 4. Possible side effects

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

- Eykappo may cause burning, stinging, itching and skin irritation (including dermatitis) around the area it has been used on. These effects are not permanent.
- Swelling of your face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema) may occur. If this happens, get medical help straight away.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Eykappo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and on the carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.

After first opening, the product may be stored for a maximum of 28 days.

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. Contents of the pack and other information

##### What Eykappo contains

- The active ingredient is chloramphenicol. Each multi-dose container contains approximately 10ml eye drops solution of chloramphenicol 5mg/ml.
- The other ingredients are borax, boric acid, sodium hydroxide or/and hydrochloric acid (for pH adjustment) and water for injections.

##### What Eykappo looks like and contents of the pack

10ml of Eykappo eye drops solution is filled in a white opaque 11ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a white HDPE cap.

Each carton contains 1 multi-dose container.

##### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

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