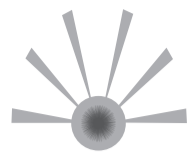


**Package leaflet:  
Information for the user**



**mollifeye**  
**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.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

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

Mollifeye 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 Mollifeye"), before using these eye drops.

**What is in this leaflet**

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

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

Mollifeye contains an antibiotic medicine called chloramphenicol. It is used in both adults and children **aged 2 years and over** to treat bacterial infections that affect the front surfaces of the eye.

The most common type of infection in this area is called acute bacterial conjunctivitis. When you have this condition, the white part of one or both of your eyes will be red and/or your eyelids will be red or swollen. There will be a sticky discharge, which can make the eye difficult to open in the morning and the eye may feel 'gritty or irritated'.

This medicine is not suitable for treating eye infections that have spread to the deeper layers of the eye coverings or into the fluid within the eyeball. Antibiotic tablets or injections are needed to treat these deeper, more serious infections.

This medicine does not contain a preservative.

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

Mollifeye eye drops are recommended for use in **children aged 2 years and over**, in adults and the **elderly**. A child below the age of 2 years with an eye infection should see a doctor.

**Do not use this medicine if:**

- you are allergic to chloramphenicol or any of the other ingredients in this medicine (listed in section 6)
- you have ever had problems with your blood (in particular very low numbers of blood cells) during previous treatment with chloramphenicol
- you have a family history of blood problems such as low white blood cell, red blood cell, or platelet counts
- you have a history of contact hypersensitivity to silver

**Warnings and precautions**

Talk to your doctor or pharmacist before using Mollifeye if:

- your eyesight is affected (loss of sight, reduced vision, blurred or double vision, or halos around lights)
- you have pain within the eye
- your eye(s) are more sensitive to light than usual
- your pupil(s) looks unusual
- your eye(s) looks cloudy
- you have pain or swelling around the eye or face
- you have had an eye infection in the recent past
- you have glaucoma (a raised pressure in the eye)
- you have very dry eyes
- you have an eye injury
- you have something in your eye
- you are already using other eye drops or eye ointment
- you have had eye surgery or laser treatment in the last 6 months
- you wear contact lenses
- you or someone in your family suffer from problems with your blood (aplastic anaemia) or bone marrow problems
- you suffer from any other eye problems
- you have ever had an allergic (hypersensitive) reaction to this or any other medicine
- you are pregnant, trying for a baby or are breastfeeding

**Other medicines and Mollifeye**

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

If you are taking bone marrow depressant drugs (drugs which decrease the activity of the bone marrow, causing low blood cell counts) such as azathioprine or are receiving chemotherapy, seek the advice of your pharmacist or your doctor before using this product.

**Pregnancy and breast-feeding**

Mollifeye should not be used if you are pregnant, trying for a baby or are breast-feeding.

**Driving and using machines**

Mollifeye can cause temporary blurring of vision after you have used it. Wait until your vision is clear before driving or using machines.

**Mollifeye contains boron**

This medicine contains 2.9mg of boron per one ml of solution.

**3. How to use Mollifeye**

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

**Contact lenses**

If you wear contact lenses they must be removed whilst you are using Mollifeye. You should wait 24 hours after you take your last dose of Mollifeye before starting to use your lenses again.

**Instructions for use**

- To be used in the eye(s) only.
- 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 or pharmacist.



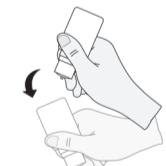
4. Blink a few times so that the drop spreads over the eye.



5. After using Mollifeye, 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 Mollifeye left in the bottle. You should not be concerned since an extra amount of Mollifeye has been added and you will get the full amount of Mollifeye 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.

**Whilst applying the drops, do not:**

- breathe on or touch the tip of the bottle
- touch the eyes or eyelids (or any other surface) with the tip of the bottle
- share your eye drops with anyone else

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

**Use this medicine only in your eyes.**



#### How much to use

##### Adults, the elderly and children over 2 years

Put one drop into the affected eye(s) every 2 hours for the first 48 hours. After this you should reduce the dose to one drop every 4 hours.

Use during waking hours only. Do not use this medicine just before you go to sleep.

The course of treatment should be 5 days. Do not use this medicine for longer than 5 days at a time.

Do not stop just because you feel better, this could make your condition worse.

Seek further immediate medical advice at any time if symptoms worsen.

Consult your doctor if your eye infection does not start to improve within 48 hours.

##### If you use more Mollifeye than you should

Mollifeye eye drops are for external use only. If you have swallowed or you suspect someone else has swallowed any Mollifeye eye drops, contact your doctor or go to the accident and emergency department of your local hospital at once. Always take the container with you, if possible, even if empty.

If you accidentally apply too many drops, you should wash your eye with plenty of water, if any painful symptoms continue after this, you should tell your doctor immediately.

##### If you forget to use Mollifeye

Try not to miss doses. If you do miss a dose do not worry, take your next dose at the normal time.

Never double up on a dose to make up for the one you have missed.

#### 4. Possible side effects

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

Some people may get one or more of these side effects. Some effects happen straight away but do not last long, others may only happen after several days of use.

- **Allergic reactions** such as itching or rashes. If you get a severe allergic reaction, with swelling or breathing problems **stop using the drops immediately** and get medical help straight away.
- Changes in the blood (anaemia) leading to **severe tiredness** or **easy bruising**. If you experience these effects, stop using the drops immediately and tell your doctor.
- The use of topical chloramphenicol may occasionally result in the overgrowth of other non susceptible organisms including fungi. If any new infection appears during treatment you should tell your doctor.
- Blurred vision or mild burning or stinging when you put the drops in. These should subside quickly.
- **Irritation of the skin** around the eyes, **mercurialness** (brown discolouration of the lens) and a **typical band keratopathy** (appearance of calcium on the cornea).

If you do not feel well or are worried about your health, talk to a pharmacist or doctor. If any of the side effects get serious or if you experience any side effect not listed in this leaflet please tell your doctor or pharmacist.

##### 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 Mollifeye

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

Do not use this medicine after the expiry date printed on the bottle label and on the carton after 'EXP'. The expiry date refers to the last day of that month. Once the bottle is opened use within 4 weeks.

You are advised to dispose of the bottle once you have finished your five day course of treatment. This medicine needs to be stored upright between 2°C - 8°C (in a refrigerator). Protect from light. Do not allow it to freeze.

Medicines should not be disposed of 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 Mollifeye 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 injection.

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

10ml of Mollifeye eye drops is filled in a white opaque plastic bottle and white Novelia nozzle that is sealed with a white HDPE cap.

Each carton contains 1 multi-dose container.

##### Marketing Authorisation Holder and Manufacturer

###### Marketing Authorisation Holder

Aspire Pharma Ltd  
Unit 4, Rotherbrook Court  
Bedford Road  
Petersfield  
Hampshire  
GU32 3QG  
United Kingdom

###### Manufacturer

Pharmathen S.A.  
6 Dervenakion  
15351 Pallini Attiki  
Greece

and

EXCELVISION  
27 st. La Lombardière  
ZI La Lombardière  
ANNONAY 07100  
France

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