

## Package leaflet: Information for the user



### 5mg/ml eye drops, solution

levofloxacin hemihydrate

**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, pharmacist or nurse.
- 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

EyfloX 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 15 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 EyfloX"), before using these eye drops.

#### What is in this leaflet

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

### 1. What EyfloX is and what it is used for

EyfloX contains a medicine called levofloxacin. Levofloxacin is an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

When levofloxacin is given in eye drops, it is used in children aged 1 year or over and in adults to treat bacterial infections that affect the front surfaces of the eye.

One type of infection in this area is called bacterial conjunctivitis, which is an infection of the covering of the front of the eye (conjunctiva).

EyfloX is not recommended to be used in children aged below 1 year.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

### 2. What you need to know before you use EyfloX

#### Do not use EyfloX:

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

If you are not sure, ask your doctor or pharmacist first.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using EyfloX:

- if an allergic reaction occurs, even after a single dose, stop using the medicine.
- if you observe worsening of your eye symptoms during treatment, please contact your doctor as soon as possible.
- if you do not see any sign of recovery within a certain treatment period agreed with your doctor, please contact your doctor as soon as possible.
- generally, no types of contact lenses should be worn when the eye is infected.

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

Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking EyfloX if you develop pain or swelling of the tendons (tendinitis).

#### Children and adolescents

The special warnings and precautions for using this medicine are the same in adults, adolescents and children aged 1 year or over.

#### Other medicines and EyfloX

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, tell your doctor or pharmacist if you are applying any other type of eye drop or eye ointment before you start to use EyfloX.

If you are using other eye drops, you should wait at least 15 minutes between applying EyfloX and any other type of eye drop.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

EyfloX eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the growing baby.

Although very small amounts of levofloxacin reach the blood and the breast milk, respectively, after instilling eye drops it is very unlikely that the eye drops would harm the growing baby. Your doctor is informed about the potential risk and will advise you whether to use EyfloX eye drops in this case.

Your fertility (ability to become pregnant or to father a child) is not impaired when you apply EyfloX following its instructions for use.

#### Driving and using machines

EyfloX has minor influence on the ability to drive and use machines.

If the eye drops cause blurring of your sight when you use them, you should wait until this clears before driving or operating machinery.

### 3. How to use EyfloX

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

EyfloX eye drops are for ocular use and have to be applied to the outer surface of the eye. For patients above 1 year of age, the recommended dose is as follows:

DAYS 1 - 2

- Use one to two drops in the affected eye(s) every two hours.
- Use a maximum of 8 times per day.

DAYS 3 - 5

- Use one to two drops in the affected eye(s).
- Use a maximum of 4 times per day.

In elderly patients no adjustment of the recommended dose is required.

The usual total treatment course is five days. Your doctor will advise you how long to apply the drops. If you are putting any other medicine in your eye, you should wait at least 15 minutes between applying the different types of drops.

#### Use in children and adolescents

No dosage modification is required in children over 1 year of age and in adolescents. EyfloX is not recommended to be used in children aged below 1 year.

#### Method of administration

Ocular use: this medicine is eye drops which are intended to be used in the eye.

Do not allow the tip of the multi-dose bottle 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 bottle, keep the tip of the multi-dose bottle away from contact with any surface.

#### 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).

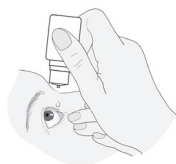
#### Instillation:

- 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 Eyflox, press a finger into the corner of your eye, by the nose for a few minutes. This helps to stop the eye drops 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 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.



After you have used all doses there will be some Eyflox left in the bottle. You should not be concerned since an extra amount of Eyflox has been added and you will get the full amount of Eyflox 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.

Eyflox eye drops should not be injected into the interior part of the eyeball.

#### **If you use more Eyflox than you should**

If you use more Eyflox than you should, flush the eye(s) with water and tell your doctor or pharmacist.

#### **If you forget to use Eyflox**

If you forget to use the eye drops, put in the next dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

#### **If you swallow Eyflox by accident**

The amount of levofloxacin in the provided bottle is too small to cause side effects. However, if you are concerned, tell your doctor or pharmacist who will advise you on any necessary measures.

**If you stop using Eyflox earlier than instructed**, it may delay the healing process.

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

### **4. Possible side effects**

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

About one in ten people have a side effect when using Eyflox. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effects you should stop using Eyflox eye drops and seek urgent advice from your doctor.

It is possible, even though rare, to develop an allergic reaction to Eyflox even after just one dose. You notice this because your eyes may become red or itchy, or the lids may be swollen. If this should happen, stop using Eyflox and contact your doctor immediately.

**Common side effects** (may affect up to 1 in 10 people):

- burning feeling in the eye
- decreased vision or mucus in the eye

**Uncommon side effects** (may affect up to 1 in 100 people):

- stinging or irritation of the eyes
- painful eyes
- dry or sore eyes
- swelling or redness (bloodshot eyes) of the conjunctivae (front covering of the eye) or eyelid
- sensitivity to light
- itchy eyes
- sticky eyelids
- headache
- rash around the eye
- stuffed or runny nose

**Rare side effects** (may affect up to 1 in 1,000 people):

- allergic reactions such as skin rash

**Very rare side effects** (may affect up to 1 in 10,000 people):

- swelling and tightness in the throat
- breathing difficulty

#### **Additional side effects in children and adolescents**

Frequency, type and severity of side effects in children and adolescents are expected to be the same as in adults.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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 Eyflox**

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 label and carton after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the plastic film around the cap and neck is missing or broken before you start a new bottle.

Do not use this medicine if you notice insoluble parts in the solution.

Store below 25°C.

Keep the bottle tightly closed. Keep the bottle in the outer carton in order to protect from light.

**To prevent infections, you must throw away the bottle 28 days after you first opened it and use a new bottle.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Eyflox contains**

- The active substance is levofloxacin.  
1ml contains 5.12mg of levofloxacin hemihydrate equivalent to 5mg of levofloxacin.
- The other ingredients of Eyflox are sodium chloride, sodium hydroxide or hydrochloric acid for pH adjustment and water for injections.

#### **What Eyflox looks like and contents of the pack**

- Eyflox is a clear, light yellow to light greenish-yellow solution, free of visible particulate matter.
- 5ml of solution is supplied in a white opaque 5ml LDPE bottle with white Novelia nozzle (HDPE and silicone) and a white HDPE cap.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Aspire Pharma Limited  
Unit 4, Rotherbrook Court  
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#### **Manufacturer**

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