

OXALUX 20 monodose da 0,5 ml (STESO)

Nome:	OXALUX 20 monodose da 0,5 ml
Tipo Carta:	USOMANO 60gr/mq bianco
F.to carta:	160x380 mm.
Piega:	NO STESO
Stampa:	1 colore NERO

Codice: 35104080-01

2 bozza
del
18-1-2021

Package leaflet: Information for the user**Oxalux Unit Dose 5 mg/ml eye drops
in single-dose container**

Levofloxacin

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.

What is in this leaflet

1. What Oxalux eye drops are and what they are used for
2. What you need to know before you use Oxalux eye drops
3. How to use Oxalux eye drops
4. Possible side effects
5. How to store Oxalux eye drops
6. Contents of the pack and other information

1. What Oxalux eye drops are and what they are used for

Oxalux eye drops contains the active ingredient levofloxacin, an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

When Oxalux 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).

Oxalux eye drops are 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 Oxalux eye drops**Do not use Oxalux eye drops**

- 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 Oxalux eye drops

- 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.

Children and adolescents

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

Other medicines and Oxalux eye drops

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 Oxalux eye drops.

If you are using other eye drops, you should wait at least 15 minutes between applying Oxalux eye drops 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 taking this medicine.

Oxalux 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 applying 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 Oxalux eye drops in this case.

Your fertility (ability to become pregnant or to father a child) is not reduced when you apply Oxalux eye drops following the instructions for use.

Driving and using machines

Oxalux eye drops have 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 Oxalux eye drops

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

Oxalux eye drops are for ocular use. **DO NOT** allow the single-dose container to touch the eye or areas around the eye. It could cause injury to your eye. It may be contaminated with bacteria that can cause infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single-dose container, wash your hands before using this medicine and keep the tip of the single-dose container away from contact with any surface. A new single-dose container should be opened immediately prior to each use; there is enough solution in each container for both eyes if your doctor has told you to use the drops in both eyes

For patients aged 1 year and over, 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 for.

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 aged 1 year or over and in adolescents. Oxalux eye drops are not recommended to be used in children aged below 1 year.






Instructions for use

If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.

- 1) Wash your hands.
- 2) Open the pouch.
- 3) Remove one single-dose container from the strip.
- 4) Put the remaining strip back in the pouch and fold the edge to close the pouch.

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 <p>5) Make sure that the solution is in the bottom part of the single-dose container.</p>	 <p>6) To open the container, twist off the tab.</p>	 <p>7) Hold the container between your thumb and index finger.</p> <p>8) Tilt your head backwards while seated, or lie down on your back.</p>	 <p>9) Place the tip of the container close to your eye. DO NOT allow any part of the container to touch your eye or any area around your eye.</p> <p>10) Pull the lower eyelid downwards and look up.</p>	 <p>11) Press the container slightly and let one drop fall in the space between the lower eyelid and the eye.</p> <p>12) Close your eye for a moment. Press the inner corner of the eye with your index finger for about one minute. This prevents the eye drop from draining down the tear duct.</p>
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If another drop is needed, and when both eyes are to be treated, repeat steps 9 to 12.

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

For single use only. The eye drops should be used immediately after first opening the single -dose container.

The contents of one single-dose container are sufficient for both eyes.

Discard container with any remaining solution after single use.

If you use more Oxalux eye drops than you should

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

If you forget to use Oxalux eye drops

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 Oxalux eye drops 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 Oxalux eye drops 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 Oxalux eye drops. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effect you should stop using these eye drops and seek urgent advice from your doctor.

Very rarely this medicine can cause severe allergic reactions. The following symptoms can occur even after just one dose of Oxalux eye drops:

- swelling and tightness in the throat
- breathing difficulties.

In rare cases other allergic reactions can develop. Symptoms of such reactions are:

- worsening of redness and itching of the eyes
- increased or sudden swelling of eyelids.

Stop using Oxalux eye drops and contact a doctor immediately if any of these symptoms occurs.

Common side effects (may affect up to 1 in 10 users)

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

Uncommon side effects (may affect up to 1 in 100 users)

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

Rare side effects (may affect up to 1 in 1,000 users)

- allergic reactions such as skin rash

Very rare side effects (may affect less than 1 in 10,000 users)

- 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, 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 at: 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 Oxalux eye drops

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 single-dose container, pouch and carton after "EXP". The expiry date refers to the last day of that month.

Oxalux eye drops containers must be stored in the original pouch in order to protect from light.

You can use Oxalux eye drops 3 months after first opening the pouch.

Discard any unused single-dose container after that time.

Discard the opened single-dose container with any remaining solution after first use immediately.

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

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 Oxalux eye drops contain

The active substance is levofloxacin. 1 ml contains 5.12 mg of levofloxacin hemihydrate equivalent to 5 mg of levofloxacin.

The other ingredients are sodium chloride, hydrochloric acid and water for injections.

What Oxalux eye drops look like and contents of the pack

Oxalux eye drops is a clear, light yellow to light greenish-yellow solution.

Single-dose containers in a strip of five are packed in a plastic/aluminium pouch.

One single-dose container contains 0.5 ml of solution.

Pack size: 20 x 0.5 ml.

Marketing Authorisation Holder

Kestrel Ophthalmics Ltd,
Unit 9, Cabot Business Village,
Holyrood Close, Creekmoor,
Poole, BH17 7BA,
United Kingdom

Manufacturer

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Other formats

To request a copy of this leaflet in Braille, large print or audio please call 01202 696963

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