Ofloxacin Unit Dose 3 mg/ml eye drops, solution

When you should not use this medicine or when you should take extra care with it.

When should you not use this medicine?

You are allergic to any of the substances in this medicine or to other quinolone antibiotics..

When should you take extra care with this medicine?

Contact your doctor or pharmacist before using this medicine if:

- You are excessively exposed to sunlight or ultraviolet light (e.g., sunlamp, tanning bed, etc.) during treatment with Ofloxacin Unit Dose.
 Both should be avoided due to a possible sensitivity to light.
- You are sensitive to other antibiotics of the quinolone type.
- You wear contact lenses. The use of contact lenses is not recommended during the treatment of an eye infection.
- This product should be used with caution in patients with damage or ulceration of the surface of the eye.

As with other antibiotics, an increase in non-sensitive pathogens may occur with prolonged treatment with Ofloxacin Unit Dose. If such an infection occurs during treatment, your doctor will take appropriate measures.

Swollen and torn tendons have been reported in people who took oral or intravenous fluoroquinolones, especially in older patients and those who were concurrently treated with corticosteroids. Stop using Ofloxacin Unit Dose if you experience painful or swollen tendons (tendinitis).

Children and adolescents under 18 years old

There is limited experience with the use of ofloxacin eye drops in children. Contact your doctor before starting to use this medicine in children.

Are you using any other medicines?

If you are using any other medicines, including recently or in the near future, in addition to Ofloxacin Unit Dose, tell your doctor or pharmacist.

If you use other eye drops/eye ointments in addition to Ofloxacin Unit Dose, you should wait for approximately 15 minutes between inserting those medicines into the eye. Ointments should always be inserted last.

Pregnancy, breastfeeding, and fertility

Are you pregnant, think you might be pregnant, want to become pregnant, or breastfeeding? Contact your doctor before using this medicine. Your doctor will advise you whether you can use this medicine.

Driving and using machines

Inserting Ofloxacin Unit Dose may cause blurred vision. These symptoms may last for a few minutes. Do not use machines, work without support, or drive a car during this time.

How to use this medicine?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage for all ages is: one drop of Ofloxacin Unit Dose in the inner side of the lower eyelid of the affected eye(s):

every 2 to 4 hours for the first two days and then 4 times a day

Consult your doctor if your eye infection worsens or does not improve within a few days.

The content of a single-use packaging is sufficient for both eyes.

Method of administration

- 1. Wash your hands.
- 2. Open the outer packaging (bag) and remove a strip with attached single-use packages.
- 3. Detach one single-use package from the strip.
- 4. Place the remaining single-use packages back in the outer packaging and close the bag by pressing the protruding part. Store the bag in the box.
- 5. Open the single-use package by twisting the tab. Be careful not to touch the opening of the single-use package after opening.
- 6. Tilt your head back.
- 7. pull down the lower eyelid with your finger and take the single-use package in the other hand.
- 8. Gently press on the package and let a drop fall into the eye
- 9. Close your eyes and press with your fingertip on the inner corner of the eye for 1-2 minutes.
- 10. This prevents the drop from running into your throat through the tear duct and keeps most of the drop in the eye (Fig. 5).
- 11. Repeat steps 6 to 8 for the other eye, if applicable.

Dispose of the single-use package after use.

Duration of treatment

Do not use this medication for more than 14 days.

Have you used too much of this medication?

There have been no reported cases of overdose. If you have accidentally instilled too many drops into an eye, rinse the eye with clean water.

If side effects occur in other parts of the body than the eye due to improper use, accidental overdose, or ingestion through the mouth, they should be treated systemically. Contact your doctor in this case.

Have you forgotten to use this medication?

Do not take a double dose to make up for a missed dose. Apply the missed dose as soon as you remember. Then continue with the same amount and interval/rhythm as mentioned above, or as prescribed by your doctor.

Do you have any other questions about using this medication? Then contact your doctor or pharmacist.

Possible side effects

Like any medication, this medication can have side effects, although not everyone experiences them. Serious side effects, frequency unknown (cannot be determined from available data):Potentially life-threatening skin rash (Stevens-Johnson syndrome, toxic epidermal necrolysis) has been reported with the use of Ofloxacin Unit Dose, initially appearing on the trunk as red bull's eye-like spots or ring-shaped spots often with blisters in the center. If an allergic reaction (including eye allergy) occurs, stop using the eye drops immediately and contact your doctor.

The following other side effects are known to occur:

Common (may affect between 1 in 10 and 1 in 100 people): Eye irritation, Discomfort in the eye

Very rarely (may occur in less than 1 in 10,000 people): Allergic reactions (including severe allergic reactions that can lead to swelling of the face, lips, tongue, throat or other parts of the body, rash and itching, breathing problems and dizziness, anaphylactic shock), Unknown frequency (frequency cannot be estimated from the available data): Dizziness, Eye inflammation, Blurred vision, Light sensitivity, Swelling of the eyes, face or around the eyes (including swelling of the eyelids), Sensation of something in the eye, Tear formation, Dry eye, Eye pain, Allergic reactions in the eye (including itchy eye or itchy eyelids), Red eyes, Nausea

How to store this medicine?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box, the outer packaging and the unit dose packaging. The expiry date refers to the last day of that month.
- After opening the aluminum outer packaging, do not use Ofloxacin Unit Dose for more than 4 weeks.
- Ofloxacin Unit Dose does not contain a preservative. You should not keep opened unit dose packages for later use. After inserting the solution, dispose of any remaining solution in the unit dose packaging.
- Store below 25°C. Do not store in the refrigerator or freezer.
- Store in the original packaging to protect from light.