PACKAGE LEAFLET: INFORMATION FOR THE USER

ZYLOTRA 0.5% + 0.3% Eye Drops, Suspension
Instilled into the eye(s)
Sterile

Active substance: Each 1 mL of eye drops contains 5 mg loteprednol etabonate (0.5%) and 3 mg tobramycin (0.3%).
Excipients: Benzalkonium chloride, glycerin, tiloxapol, povidone, disodium edetate, sulfuric acid, sodium hydroxide, water for injection.

Read all of this PACKAGE 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; do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you use this medicine when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a* ***higher or lower*** *dose other than recommended to you.*

In this leaflet:

1. WHAT ZYLOTRA IS AND WHAT IT IS USED FOR

ZYLOTRA is an eye drop containing 5 mg loteprednol etabonate and 3 mg tobramycin in each mL as active ingredient. Loteprednol etabonate belongs to a group of medicines called corticosteroids, which are used to treat inflammatory conditions in the body. Tobramycin is an antibiotic and is used to treat bacterial infections.

ZYLOTRA contains 5 mL of white to yellowish-white suspension without foreign particles and is available in opaque, white colored, low-density polyethylene (LDPE) bottles with a dropper.

ZYLOTRA should be instilled into the eye and used for the treatment of superficial infections of the eye caused by susceptible bacteria or inflammatory conditions that cause a risk of infection.

Your doctor may have prescribed ZYLOTRA for you to treat bacterial conjunctivitis in your eye.

Bacterial conjunctivitis is an infection caused by bacteria in the conjunctiva, which covers the front surface of the eye and the inner surface of the eyelid.

The disease occurs with symptoms such as redness in the affected eye, edema (swelling) on the eyelids, inflammatory discharge, burrs and sometimes pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ZYLOTRA

Do not use ZYLOTRA

- If you are allergic or suspected of being allergic to any of the ingredients in ZYLOTRA or to other corticosteroids (medicines used to treat inflammatory conditions in the body).
- If you have an infection due to the Herpes simplex virus or other viruses that affect the membrane covering the inner part of the eye and eyelid (conjunctiva) and/or the transparent layer of the eye (cornea).
- If you have fungal or tuberculosis infections in your eyes.

ZYLOTRA should not be dripped with a syringe, should be instilled only.

Take special care with ZYLOTRA

Long-term use of corticosteroids may result in optic nerve damage, visual acuity and visual field defects, and cataracts. If your eye pressure is high, it should be used with caution; in this case, consult your doctor before use.

An allergy to tobramycin may also develop. In this case, stop using this medicine. If you are allergic to any antibiotic from the aminoglycoside group to which tobramycin belongs, you may also be allergic to tobramycin.

Long-term use of corticosteroids can suppress the body's immune response, prolong the course of the disease, mask infection, and exacerbate various infections due to viruses, bacteria, and fungi. When such infections occur, consult your doctor for appropriate treatment to be started.

If you have previously had an eye infection caused by the Herpes simplex virus, care should be taken when using a medicine containing corticosteroids, and consult your doctor about it.

Corticosteroid use after cataract surgery may delay healing.

If this product is used for 10 days or longer, eye pressure should be measured in patients with difficult cooperation and even in children although it is difficult to apply.

If you are taking tobramycin for eye discomfort at the same time you are taking aminoglycoside antibiotics, either by mouth or by injection, it may be necessary to monitor the level of the medicine in your blood. In such a situation, consult your doctor.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using ZYLOTRA with food and drink

ZYLOTRA is not known to interact with any food.

Pregnancy

Consult your doctor or pharmacist before using this medicine.
It is not known whether ZYLOTRA is safe for use during pregnancy. Therefore, it should not be used during pregnancy unless it is certain that the benefits outweigh the risks.
If you realize that you are pregnant during your treatment, consult to your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before using this medicine.
Since it is not known whether use of corticosteroids in the eyes passes into breast milk, caution should be exercised when using ZYLOTRA in nursing mothers.

Driving and using machines
No information is available on the effects of the medicine on the ability to drive and operate machinery. However, as with all eye medicines, do not drive or operate machinery if temporary blurred vision occurs when the medicine is used. Wait before driving or using machines until your vision clears again.

Important information about some of the ingredients of ZYLOTRA
Benzalkonium chloride may cause eye irritation. Avoid contact of the medicine with soft contact lenses. Remove your contact lenses before application and wait at least 15 minutes before putting them back on. This ingredient is also known to discolor soft contact lenses.

Other medicines and ZYLOTRA
No information is available on the interaction of other medicines when used in combination with ZYLOTRA that is applied topically to the eye.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. HOW TO USE ZYLOTRA

Instructions for proper use and dosage/frequency of administration
Shake the bottle well before use.
Instill 1 or 2 drops in the conjunctival sac (inner side of the lower eyelid) of the affected eye(s) every 4-6 hours. In the first 24-48 hours, you can instill 1 drop in 1-2 hours. The instillation frequency should be gradually reduced according to the improvement in clinical signs.

Safety and efficacy in pediatric patients have not been evaluated. No differences in safety and efficacy were observed between elderly and younger patients.

During the use of ZYLOTRA, the tip of the dropper should not come into contact with any surface in order to prevent the transmission of microbes. Consult your doctor if pain, redness, itching or inflammation develops or worsens.

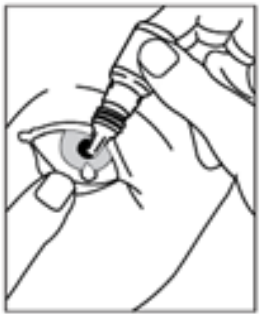
This medicine is for use in the eye only. The decision to start the treatment and, if necessary, to repeat the treatment after 14 days will be made after you have been examined by your doctor. If there is no improvement in signs and symptoms after 2 days, consult your doctor.

Your doctor will tell you how long your treatment with ZYLOTRA will last. Do not stop your treatment early. Follow these instructions unless your doctor advises otherwise.

After the bottle was first opened, the product should be used within 30 days and then discarded.

Do not forget to take your medicine.

Route and method of administration
1. Wash your hands and sit in a comfortable position.
2. Open the cap of the bottle.



3. Gently pull the lower lid of the affected eye downwards using your finger.
4. Bring the tip of the dropper close to the eye, but do not touch the eye.
5. Squeeze the dropper gently and put ONLY one drop into the eye. Then release the lower eyelid.
6. Press the corner of the eye on the nose side with your finger. Keep your eyes closed in this way for about a minute.
7. If your doctor has told you to use the medicine for both eyes, repeat the same procedures for your other eye as well.
8. Close the bottle.

If your doctor has prescribed other medicine for you to drip into the eye, instill these two medicines at least 5 minutes apart.

Different age groups
Use in children
In pediatric patients, it was found to be the same efficacy as warm compresses in eyelid inflammation. It is safe to use in this age group.

ZYLOTRA is not recommended for use in infants and young children unless it is necessary.

Use in the elderly
There are no specific reports on its use in the elderly.

Use in special conditions
Kidney/Liver failure
There are no specific reports of kidney/liver failure.

If you have the impression that the effect of ZYLOTRA is too strong or too weak, talk to your doctor or pharmacist.

If you use more ZYLOTRA than you should
Please talk to a doctor or pharmacist if you have used more ZYLOTRA *than you should.*

If you forget to use ZYLOTRA
Do not take a double dose to make up for a forgotten dose.

Possible effects when you stop using ZYLOTRA
No effect is expected when you stop using ZYLOTRA.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects can be observed in patients who are sensitive to the ingredients of ZYLOTRA.

Stop using ZYLOTRA and contact your doctor IMMEDIATELY or go to the emergency department of the nearest hospital if you experience any of the following:
- Hypersensitivity reactions
- Swelling of the hands, feet, wrists/ankles, face, lips, or especially swelling of the mouth or throat that makes it difficult to swallow or breathe.

All of these are very serious side effects. If you have any of these, it means you have a serious allergy to ZYLOTRA. You may need immediate medical attention or hospitalization. All of these serious side effects are very rare.

Side effects are listed as categorized below:
Very common : affects at least 1 in 10 patients
Common : affects 1 to 10 patients in 100
Uncommon : affects 1 to 10 patients in 1,000
Rare : affects 1 to 10 patients in 10,000
Very rare : affects less than 1 patient in 10,000
Not known : cannot be estimated from the available data.

Common
- Tearing
- Superficial punctate keratitis (a type of inflammation of thetransparent layer in front of the pupil)
- Increased eye pressure
- Burning and stinging
- Eyelid itching and swelling with hypersensitivity
- Localized ocular toxicity including conjunctival erythema (localized eye damage due to chemical action, including redness of the transparent membrane covering the inner surface of the eyelids and the anterior surface of the eyeball)
- Headache

Uncommon
- Visual disturbances
- Eye discharge
- Itchy eye
- Increased tear secretion or a feeling of dryness in the eyes
- Photophobia (sensitivity to light)
- Corneal (the transparent layer at the front of the pupil) deposits
- Eye discomfort
- Eyelid discomfort
- Other ailments in the eye

Rare

- Increased pressure in the eyes that can cause eye nerve damage, or defects in visual acuity and fields of vision
- Cataract formation (reduced lens transparency at the back of the eye lens)
- Delayed wound healing, eye infections caused by various infectious agents including Herpes simplex, or eyeball perforation in the area where the cornea (the transparent layer in front of the pupil) or sclera (the white parts of the eyes) is thinned
- Increased pressure in the eyes (≥10 mmHg)

Not known
- Secondary infections
- Fungal infections

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZYLOTRA

Keep ZYLOTRA out of the reach and sight of children and in its original package.
Store below 25°C at room temperature.

Once opened, the medicine should be used within 30 days provided that it is kept below 25°C.
Use it in accordance with the expiry date.

Do not use ZYLOTRA after the expiry date, which is stated on the pack.
Do not use ZYLOTRA if you notice any defects in the product and/or its package.

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.

Marketing Authorization Holder:
DEVA Holding A.Ş.
Küçükçekmece - ISTANBUL/TURKEY

Manufacturing Site
DEVA Holding A.Ş.
Kapaklı - TEKIRDAG/TURKEY

This package leaflet was approved on 14/01/2022.