PATIENT INFORMATION LEAFLET

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITE AND TENDON RUNNING, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM AFFECTS AND INFLUENCE OF MYASTHENIA GRAVIS

• Fluoroquinolones, including Zaridinex, can cause irreversible adverse reactions leading to disability such as:

o Tendonitis and tendon rupture

o Peripheral neuropathy

o Central nervous system effects

Zaridinex should be discontinued immediately in patients with any of these reactions and fluoroquinolone should be avoided.

• Fluoroquinolones, including Zaridinex, may exacerbate muscle weakness in patients with myasthenia gravis. Zaridinex should be avoided in those with known myasthenia gravis traces.

ZARİDİNEX 0.3% Sterile Eye Drops
Dropped into eye

- ***Active ingredient:*** Each 1 ml contains 3 mg Ofloxacin

- ***Excipients:*** Benzalkonium chloride (50% solution), sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and quantity sufficient water for injection.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine., because it contains important information for you.

- *Keep this patient information leaflet. You may need to read it again later.*
- *If you have any further questions, consult your doctor or pharmacist.*
- *This medicine is prescribed for you individually, do not pass it on to others.*
- *During usage of this medicine, when you go to a doctor or a hospital tell your doctor that you are using this medicine.*
- *Follow these instructions exactly. Do not use **higher or lower dosages** of this medicine except for recommended dosages.*

In this patient information leaflet:

1.What is ZARİDİNEX and what is it used for?

ZARİDİNEX is a transparent, foreign matter-free, light yellow, scentless, homogenious eye drop that is found in 5 ml plastic bottles. It contains ofloxacin as active ingredient. Ofloxacin is a member of medicine group called quinolones and is effective against bacteria that cause infection in eye.

ZARİDİNEX is indicated for the treatment of external ocular infections (conjunctivitis, blepharitis, sty) in adults and children.

2.What you need to know before using ZARİDİNEX

Do not use ZARİDİNEX in following conditions:

- If you are **allergic** (hypersensitive) to **ofloxacin, benzalkonium chloride,** any of the other ingredients, or any other quinolones.
- If your child is under age 1.
- If you are pregnant, if it is possible that you are pregnant or if you are breast-feeding.

Use ZARİDİNEX CAREFULLY in following conditions:
If;

- Allergic reactions occur like swelling of your face and throat, breathing difficulty, rash and itch while you use ZARİDİNEX.
- These kinds of symptoms occur, stop using the drug and immediately inform your doctor. If you have shown allergic reactions to any other quinolone group antibiotics, use ZARİDİNEX carefully.
- Your condition gets worse or there is no recovery occurs; prolonged usage can cause evolution of antibiotic resistant bacteria. For this reason if sufficient improvement is not seen at the end of the treatment period, please consult your doctor.
- You have cornea epithel defect or cornea ulcer.
- You are using soft contact lenses;

ZARİDİNEX contains benzalkonium chloride which may cause soft contact lenses discoloration. Patients must avoid contacting contact lenses with the medicine. Therefore patients must be warned about taking out the lenses before administrating the medicine and not to put back on before 15 minutes.

ZARİDİNEX contains benzalkonium chloride which may cause irritation in eye. Sedimentation can occur in cornea during ZARİDİNEX treatment.

ZARİDİNEX must not be administrated by injection.

If these precautions are valid also for past, consult your doctor.

Using ZARİDİNEX with food and drink
There is no interaction with food and drink expected.

Pregnancy
Consult your doctor or pharmacist before using this medicine.
ZARİDİNEX is not recommended to be used during pregnancy.
If you notice you are pregnant during the treatment, immediately consult your doctor or pharmacist.

Lactation
Consult your doctor or pharmacist before using this medicine.
ZARİDİNEX is not recommended to be used during breastfeeding.

Driving and using machines
Your sight may become blurred for a short time just after using ZARİDİNEX. You should not drive or use machines until your sight is clear again.

Important information about some of the ingredients of ZARİDİNEX
Normally you should not wear contact lenses whilst being treated with this product. However, there may be situations where use of contact lenses is unavoidable. In these situations remove the lenses before using ZARİDİNEX. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
A preservative in ZARİDİNEX(benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

ZARİDİNEX contains sodium. However there is no side effect expected due to administration route.

Usage with other medicines
If you are going to use ZARİDİNEX with another eye drop, there must be 15 minutes of break between two drug administrations.

If you have been using prescribed or non-prescribed medicines until now or you have used in the past, please inform your doctor about these.

3.How to use ZARİDİNEX

Instructions for proper use and dosage/administration frequency:
Always use ZARİDİNEX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is **1** or **2 drops** into the affected eye(s) every **2** to **4 hours** for the first **2 days** and then 1-2 drops **4 times a day** from then on.

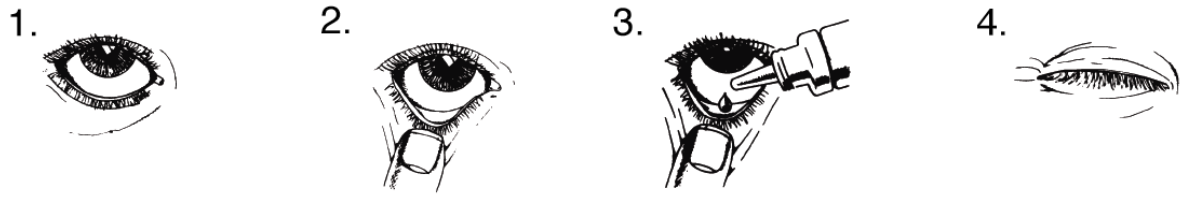
In treatments which exceed ten days, it is necessary to consult an eye doctor.

Take out your contact lenses before you use ZARİDİNEX. You can put your lenses back 15 minutes after the administration.

Administration route and method:

Wash your hands before using medicine. Apply the eye drop as described below:

1. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket
3. Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.
4. Let go of the lower lid, and close your eye for 30 seconds



If a drop misses your eye, try again.

Do not contact the tip of the dropper to your eye or any other place.

Replace and tighten the cap straight after use.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

Different age groups:
Usage in children:
Must not be used on children under age 1. Prolonged usage can cause a new bacterial infection which can not be treated with ZARİDİNEX.

Usage in geriatrics:
There is no comparative data about usage in geriatrics and other groups.

Special usage conditions:

Severe adverse reactions that cause disability, including the effects of tendinitis and tendon rupture, peripheral neuropathy and central nervous system, and potential irreversible adverse reactions

Fluoroquinolones, including Zaridinex, have been associated with potentially irreversible serious adverse reactions which can lead to disability. Common adverse reactions include, musculoskeletal and peripheral nervous system (such as tendonitis, tendon rupture, tendon swelling and inflammation, tingling or numbness, numbness in arms and legs, muscle pain, muscle weakness, joint pain, joint swelling) arthralgia, myalgia, peripheral neuropathy and central nervous system effects (hallucinations, anxiety, depression, suicidal tendency, insomnia, severe headache and confusion) (see section 4)

These reactions can be seen in hours or weeks after ZARIDINEX starts. Patients of all age groups, or those who do not have pre-existing risk factors, experience these adverse reactions. ZARIDINEX should be discontinued immediately in case of any first signs or symptoms of serious adverse reactions. In addition, fluoroquinolones, including ZARIDINEX, should be avoided in patients with any of these serious adverse reactions associated with fluoroquinolones.

Renal / Liver impairment:
There is no special statement about eye drop administration in patients with renal/liver impairment.

If you have notice that effects of ZARİDİNEX is too low or too high, contact your doctor or pharmacist.

If you have used more than required dosages of ZARİDİNEX:
There is no adverse effect due to overdose expected.

If you have taken more than required dose of ZARİDİNEX, apply your next dose at the normal time.

If you have taken more than required dosages of ZARİDİNEX, contact your doctor or pharmacist.

If you forget to use ZARİDİNEX:
If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose.
Then apply your next dose as usual and continue with your normal routine.

Do not use a double dose to make up for a forgotten dose.

Possible effects at the end of the ZARİDİNEX treatment:
When ZARİDİNEX treatment ends, no adverse effects are expected.

4.What are possible side effects

Like all other medicines, side effects can be seen in patients who are sensitive to ingredients of ZARİDİNEX.

Side effects are categorised below:

Very common : more than 1 in 10 people are affected
Common : fewer than 1 in 10 and more than 1 in 100 people are affected
Uncommon : fewer than 1 in 100 and more than 1 in 1,000 people are affected
Rare : fewer than 1 in 1,000 and more than 1 in 10,000 people are affected
Very rare : fewer than 1 in 10,000 people are affected
Not known : cannot be estimated from available data

Common:

- Eye irritation, ocular discomfort

Very rare:

- Hyper-sensitivity (including swelling on face and throat due to allergy (angioedema), asthma, dyspnea, immediate hyper-sensitivity reaction (anaphylactic reaction)/shock, swelling in mouth and esophagus (oropharyngeal swelling), swelling of tongue)

Not known:

- Dizziness, headache, sense decrease (hypoesthesia)
- Cornea infection (Keratitis)
- Conjunctiva infection (infection in eye surface)
- Blurred vision
- Photophobia (sensitivity to light)
- Oedema in eyelid
- A feeling that something is in your eye
- Increase in teardrop amount
- Eye dryness
- Eye pain
- Itching in eye and eyelids
- Redness in eye
- Nausea
- Oedema in eye environment
- Oedema in face

Reporting of side effects
If you notice any side effects listed or not listed in this leaflet, please tell your doctor or pharmacist. Furthermore report the side effects you feel by clicking "Reporting Medicine Side Effect" in www.titck.gov.tr or by calling 0 800 314 00 08 side effect report line Turkey Pharmacovigilance Center. By reporting side effects you can help provide more information on the safety of this medicine.
If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5.How to store ZARİDİNEX:

Keep out of the reach and sight of children.

Once you have opened the bottle do not use it longer than 28 days, even if there is solution remaining.

Store at room temperature, below 25°C.

Do not use ZARİDİNEX if you notice the tamper-proof seal on the bottle is broken.

Use conforming to expiry date.

Do not use ZARİDİNEX after expiry date on packaging.

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This patient information leaflet is approved on *01/08/2018*