Drug Information Sheet("Kusuri-no-Shiori")

External
Revised: 07/2021

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: OZEX ophthalmic solution 0.3%

Active ingredient: Tosufloxacin tosilate hydrate

Dosage form: colorless and clear ophthalmic solution (in 5 mL plastic container), (bottle) colorless, (cap) blue

Imprint or print on wrapping:

Effects of this medicine

This medicine is a new quinolone antimicrobial agent to inhibit DNA replication of bacteria and shows bactericidal action.

It is usually used to treat blepharitis/dacryocystitis/sty/conjunctivitis/tarsadenitis/keratitis. It is also used for sterilization therapy in the perioperative period of eye surgery.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
  If you wear contact lenses.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults and children, apply 1 drop at a time, 3 times a day. The dosage may be adjusted according to your disease or symptoms. Strictly follow the instructions.
- This medicine is only intended for ophthalmic use. To prevent contamination, make sure not to let the tip of eye dropper touch any part of your eye when applying.
- As a general rule, apply this medicine with the head tilted back. After applying, close your eyes softly, press the inner corner of your eyes gently for 1 to 5 minutes, and then open your eyes.
- If you need to use other eye drops at the same time, wait at least 5 minutes before applying the other eyedrop.
- If you miss a dose, apply the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should not apply two doses at one time.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- If you apply the medicine when you are wearing soft contact lens, the lens may become clouded.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include eye irritation and corneal disorder such as punctate keratitis. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- erythema, respiratory distress, swelling of eyelids [shock, anaphylaxis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store away from direct sunlight and heat.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.