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

External Revised: 06/2023

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: GATIFLO OPHTHALMIC SOLUTION 0.3%**

Active ingredient: Gatifloxacin hydrate

Dosage form: limpid and pale yellow ophthalmic solution, (volume)5mL

Imprint or print on wrapping:

## Effects of this medicine

This medicine inhibits synthesis of bacterial DNA, and shows antibacterial action.

It is usually used in the treatment of eye infections such as conjunctivitis and hordeolum, and for the sterilization before and after 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))
- For eye infections such as conjunctivitis and hordeolum: In general, apply 1 drop at a time, 3 times a day. The dosage may be adjusted according to the symptoms.

<u>Before and after eye surgery</u>: In general, before surgery, apply 1 drop at a time, 5 times a day, and after surgery, apply 1 drop at a time, 3 times a day.

In any case, strictly follow the instructions.

- •Before applying, wash your hands with soap and water. Apply the medicine so the tip of eye dropper does not touch the surface of your eye. After applying, close your eyes for 1 to 5 minutes, pressing gently on the inner corner of the eye with your finger. Wipe off any excess liquid with a clean gauze or tissue immediately.
- $\cdot$ If you need to apply other eye drops at the same time, wait more than 5 minutes.
- •If you miss a dose, apply a dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should not apply two doses at one time.
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop using this medicine unless your doctor instructs you to do so.

#### Precautions while taking this medicine

• If the medicine flows into the mouth through the nasolacrimal duct, you feel bitter taste.

# Possible adverse reactions to this medicine

The most commonly reported adverse reactions include stinging eyes, itchy eyes, hives, blurred vision, punctate keratitis (foreign-body sensation, eye pain, sensitive to bright light, lacrimation), iritis (eye pain, conjunctival hyperemia, blurred vision, focus disorder, sensitive to bright light), blepharitis (eyelid inflammation), conjunctivitis, conjunctival haemorrhage (redness of eye/the inner eyelid), lacrimation and nasal discharge (runny nose). 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.

·hives, breathing difficulty, dizziness on standing up, lightheadedness, swelling around eyes [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 at room temperature (1 to 30°C), away from direct sunlight.
- •Discard the remainder. Do not store them. If you do not know how to discard of it, please ask your pharmacy or medical institution on how to discard them. Do not give it to others.
- •To avoid improper use and quality change, do not transfer this solution to any other bottle or container.
- •Do not use any other solution in this bottle.

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For further information, talk to your doctor or pharmacist.