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

External

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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: LOMEFLON SOLUTION FOR EAR 0.3%**

 $\textbf{Active ingredient:} Lome flox a cin\ hydrochloride$ 

Dosage form:pale yellow limpid aqueous ear solution

Print on wrapping:ロメフロン耳科用液 0.3%

#### Effects of this medicine

This medicine is newquinolone antibiotic. It inhibits DNA synthesis of bacteria which causes infection, and shows antibacterial action.

It is usually used to treat otitis externa and otitis media.

### Before 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.
- •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, instill 6 to 10 drops into the ear canal at a time, twice a day. After instillation, keep the ear facing up for 10 minutes to allow absorption of the medicine. The dosage may be adjusted according to the symptoms. Strictly follow the instructions.
- ·Use this medicine only for ear dropping.
- •Warm the medicine to body temperature as far as possible. Instillation of cold medicine into the ear may cause dizziness. Lie on your side with the affected ear up and instill the medicine into the ear canal carefully, so that the dropper tip does not touch the ear. After instillation, wake up covering your ear with a clean gauze and wipe off any excess liquid.
- If you miss a dose, use the missed dose as soon as possible. However, it is needed to take an interval as long as possible before the next dose.
- · 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

### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include: ear canal itchness, ear pain in instilling, irritating sensation, decreased hearing(transient), rash and hypersensitivity. 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.

•respiratory distress, facial edema, hives [shock, anaphylactoid symptoms]

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 the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- •Discard the remainder. Do not store them.
- •Do not replace this medicine in other containers (misuse and changes in quality may occur otherwise).
- •Do not use the container for other purposes.

### For healthcare professional use only

For further information, talk to your doctor or pharmacist.