

# 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:**COMLEX OTIC SOLUTION 1.5%

**Active ingredient:**Levofloxacin hydrate

**Dosage form:**faint yellow to yellow limpid otic solution

**Imprint or print on wrapping:**



## Effects of this medicine

This medicine is a quinolone antibacterial otic agent. It inhibits the synthesis of bacterial DNA to shows antibacterial effects.

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

## 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 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, apply 6 to 10 drops at a time, twice a day by ear dropping (\*). After applying, keep the instilled medicine inside the ear canal for approximately 10 minutes (\*). The dose frequency may be adjusted according to the symptoms. Strictly follow the instructions.
  - \*How to do ear drops and an ear instillation:
    - 1) Follow your doctor's instructions to remove dirt from the ear entrance area with a tissue or cotton swab. Hold the container in your hand before use so that the liquid is close to the body temperature. Ear instillation of a cold solution may cause dizziness.
    - 2) Lie down with the ear to be treated facing up and maintain the position and apply drops which the amount of medication prescribed by your doctor (ear drops). Pay attention so that the tip of the container does not touch your ear directly when applying.
    - 3) Patients with otitis media should press several times on the protrusion in front of the ear canal while pulling back the top of the ear (earlobe) to allow the medicine to reach the inside of the ear.
    - 4) After applying, keep the instilled medicine inside the ear canal for approximately 10 minutes (lie down with the ear to be treated facing up and maintain the position) (ear instillation).
    - 5) After lying down for 10 minutes, cover your ear with a clean gauze or tissue, get up and then wipe off any excess liquid. After applying, wash your hands with soap and water.
  - 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. 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.
- If accidentally dropped in eye, rinse the eye well with water. If there is any discomfort afterward, we recommend that you see an ophthalmologist.

## Precautions while taking this medicine

- You may experience dizziness if the temperature of the medicinal liquid is low on application. Hold the container in your hand before use so that the liquid is close to the body temperature. Do not put the product in hot water, blow warm air, or use tools to heat the product.
- Since children are often unable to communicate their subjective symptoms, parents should contact their doctor or pharmacist immediately if they feel something is wrong.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include inflammation of the external ear caused by mold or other factors (fungal otitis externa), vertigo, dizziness, diarrhea, and application site ear pain. 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.**

- pallor face, cold sweat, respiratory distress [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 in a light shielding condition (in an orange shaded bag). Store at room temperature (1 to 30 degrees Celsius). If you don't have a shaded bag, store away from light.
- Discard the remainder, do not store them. If you don't know how to discard them, ask the pharmacy or medical institution where you received them. Do not give this medicine to anyone else.
- To avoid improper use (misuse) and quality loss (change), do not transfer this solution to any other bottle or container.
- Do not put any other solution in this bottle.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.