

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

Internal

Revised: 02/2016

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:** LEVOFLOXACIN TABLETS 250mg 「OHARA」

**Active ingredient:** Levofloxacin hydrate

**Dosage form:** yellow tablet, major axis: 13.6 mm, minor axis: 6.6 mm, thickness: 4.0 mm

**Print on wrapping:** レボフロキサシン 250 mg 「オーハラ」, Levofloxacin 250 mg 「OHARA」, 抗菌製剤



## Effects of this medicine

This medicine is a new quinolone antibacterial agent that inhibits DNA replication in bacteria and shows bactericidal effects.

It is usually used to treat a wide range of infections, such as infections of the skin, respiratory system, urinary/genital system, digestive system, ears and nose, or ocular or dental infections.

## 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 have renal dysfunction, heart diseases (arrhythmia, ischemic heart disease, etc.) or myasthenia gravis.  
If you have or have past medical history of convulsive diseases such as epilepsy.
- If you are pregnant, possibly 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, take 2 tablets (500 mg as levofloxacin) at a time, once a day. The dosage may be decreased according to the types of infection and symptoms. For pulmonary tuberculosis and other tuberculosis, take this medicine with other antituberculosis medicines in principle.  
For typhoid and paratyphoid: In general, for adults, take 2 tablets (500 mg as levofloxacin) at a time, once a day for 14 days.  
In any case, strictly follow the instructions.
- If you miss a dose, take 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 never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- As disturbance of consciousness may occur, pay attention when operating dangerous machinery, such as driving a car.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, sleeplessness, dizziness, headache, nausea, vomiting, diarrhea, abdominal discomfort and abdominal 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.**

- erythema, chill, respiratory distress, facial pallor, cold sweat [shock, anaphylaxis]
- fever, erythema, blister, erosion [toxic epidermal necrolysis, oculomucocutaneous syndrome]
- fever, general malaise, decreased urine output, edema of limbs or face [acute renal failure, interstitial nephritis]
- nausea/vomiting, loss of appetite, malaise, itch, yellow discoloration of the skin and the white of eyes [fulminant hepatitis, liver dysfunction, jaundice]
- fever, sore throat, general malaise, bleeding tendency (gum bleeding, nose bleeding, subcutaneous bleeding, etc.) [pancytopenia, agranulocytosis, hemolytic anemia, decreased platelets]

**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, heat and moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

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