

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

Internal

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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: LEVOFLOXACIN TABLETS 500mg "CEO"

Active ingredient: Levofloxacin hydrate

Dosage form: light orange oval tablet, major axis: 16.2 mm, minor axis: 8.0 mm, thickness: approx. 5.7 mm

Print on wrapping: (face) レボフロキサシン錠 500mg「CEO」

(back) LEVOFLOXACIN TABLETS 500mg「CEO」, レボフロキサシン錠, 500mg, 抗菌剤



Effects of this medicine

This medicine is a new quinolone oral antibacterial agent which inhibits DNA replication of bacteria during infectious episodes and shows bactericidal effect.

It is usually used to treat wide range of infections such as

otological/skin/respiratory/urinary/gynecologic/ophthalmic/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, cardiovascular diseases (arrhythmia, ischemic heart disease, etc.) or myasthenia gravis.
- If you have convulsive disorders such as epilepsy or have a history of it.
- 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 1 tablet (500 mg as levofloxacin) at a time, once a day. The dose may be adjusted according to the type of infection and symptoms.
Typhoid and paratyphoid: In general, for adults, take 1 tablet (500 mg) 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. If it is almost time for the next dose, skip the missed dose and continue 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

- This medicine may cause consciousness disorder. Pay close attention when you operate dangerous machinery such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, insomnia, 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, breathing difficulty [shock, anaphylaxis]
- fever, erythema, blister, skin erosion [toxic epidermal necrosis, mucocutaneous ocular syndrome]
- fitful muscular contraction [convulsion]
- palpitation, chest pain, discomfort in chest [QT prolongation, ventricular tachycardia]
- fever, general malaise, decreased urine output, edema of limbs or face [acute renal failure, interstitial nephritis]

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.