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:OFLOXACIN OTIC SOLUTION 0.3% "CEO"**  **Active ingredient:**Ofloxacin  **Dosage form:**faint yellow to pale yellow limpid aqueous otic solution  **Print on wrapping:** |  |
| **Effects of this medicine**  This medicine is a new quinolone antibacterial otic agent that inhibits DNA replication of bacteria and shows antibacterial effects.  It is usually used to treat external otitis 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, for adults, apply 6 to 10 drops at a time in your ear, twice a day. 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). The dose frequency may be adjusted according to the symptoms. For children, the number of drops may be reduced. Strictly follow the instructions.  ・Use this medicine only to the ear.  ・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. Also, pay attention so that the tip of the container does not touch your ear directly when applying. After lying down for 10 minutes, cover your ear with a clean gauze, get up and then wipe off any excess liquid.  ・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. | |
| **Precautions while taking this medicine** | |
| **Possible adverse reactions to this medicine**  The most commonly reported adverse reactions include ear pain and headache. 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.**  No pertinent entries.  **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.  ・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.