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

External

Revised: 12/2021

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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:BESTRON FOR EAR AND NOSE 1% (50mg)**  **Active ingredient:**Cefmenoxime hydrochloride  **Dosage form:**(powder) white to orangish pale yellow, (solvent) limpid and colorless, (after dissolution) colorless to pale yellow limpid topical solution  **Print on wrapping:**ベストロン耳科用液1% |  |
| **Effects of this medicine**  This medicine is cephem antibiotic. It inhibits synthesis of bacterial cell wall components and shows bactericidal action.  It is usually used to treat otitis externa, otitis media and sinusitis. | |
| **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))  ・For otitis externa and otitis media:Dissolve 10 mg (titer) of the active ingredient per 1 mL of the provided solution. Then 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.  For sinusitis: Dissolve 10 mg (titer) of the the active ingredient per 1 mL of the provided solution. Then inhale 2 to 4 mL with a nebulizer at a time, once every other day, 3 times a week, or instill 1 mL into the maxillary sinus, once a week.  The dosage may be adjusted according to the symptoms in any case. Strictly follow the instructions.  ・Warm the solution to room temperature. Instillation of cold solution into the ear may cause dizziness. Lie on your side with the affected ear up and instill the solution into the ear canal carefully, not to touch the dropper tip directly the ear and remain still for 10 minutes. Apply clean gauze to the ear and wipe off residual solution that may drip out of the ear when you sit up.  ・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. You should never use two doses at one time.  ・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 wheezing (whistling sound), cough, rhinitis (nasal discharge, sneeze), vomiting, nausea, rash and headache in rhinology, and eczema in the external auditory canal, ear pain in instilling and rash in otology. 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.**  ・hives, cyanosis (skin, lips, and nails turning bluish purple), sweating [shock, anaphylaxis]  ・sudden shortness of breath, wheezing (whistling sound), difficult to breathe [asthma attack, breathing difficulty]  **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**  ・Store the medicine at room temperature (1 to 30℃) out of the reach of infants and children, away from direct sunlight. Store the solution in which the powder is dissolved in a cool place (1 to 15℃) and use it within 7 days. Using the solution with a nebulizer at room temperature, use it within 20 hours after dissolution.  ・Discard the remainder. Do not store them.  ・To avoid improper use and quality 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.