

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

Internal

Revised: 07/2022

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:ZYVOX Tablets 600mg

Active ingredient:Linezolid

Dosage form:white to faintly yellowish white tablet, major axis: 18 mm, minor axis: 10 mm, thickness: 6 mm

Imprint or print on wrapping:ZYVOX 600mg, ザイボックス, 600 ZYV, ザイボックス 600mg



Effects of this medicine

This medicine is an oxazolidinone antibiotic and exerts antibacterial effect by inhibiting protein synthesis initiation of bacteria.

It is usually used to treat infections caused by vancomycin-resistant *Enterococcus faecium* (VRE), and pneumonia, skin infections and sepsis caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Not effective against fungal or virus infection.

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 have myelosuppression such as anemia or renal dysfunction.
If your body weight is less than 40 kg.
If you receive hemodialysis.
- 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 adults and children aged 12 years or over: In general, take 1 tablet (600 mg of the active ingredient) at a time, twice a day, every 12 hours.
For children under 12 years of age: In general, take 10 mg/kg of the active ingredient at a time, every 8 hours.
However, each dose should not exceed 600 mg. This preparation contains 600 mg of the active ingredient in a tablet.
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 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

- Blood test may be periodically performed (approximately once a week) since myelosuppression may occur.
- Acidosis may occur. If symptoms of nausea and vomiting repeatedly occur, contact your doctor immediately.
- Hyponatremia may occur. Blood test may be periodically performed.
- Pseudomembranous colitis, a serious colitis with fulminant diarrhea as a prominent symptom accompanied by fever, abdominal pain, increased white blood cell and mucoid/bloody stool may occur in rare cases. If you experience abdominal pain or frequent diarrhea while taking this medicine or in 2 to 3 weeks after completion of this medicine, contact your doctor immediately.
- If you take this medicine for longer than 28 days, optic nerve disorder may occur and further progress to vision loss. If you notice symptoms such as decline in visual acuity, color blindness (difficulty in seeing color differences), blurred vision (hazy vision) and visual field defect (defect in the visual field), contact your doctor immediately.
- Increased blood pressure or palpitation may occur. Avoid taking excessive amounts of tyramine-rich food including cheese, beer or red wine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include bleeding tendency (gingival or nose bleeding)/prolonged bleeding, anemia, diarrhea and rash. 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.

- anemia symptoms (dizziness on standing up, headache), fever, bleeding tendency (subcutaneous or nose bleeding) [myelosuppression]
- nausea/vomiting, over breathing, decreased consciousness [metabolic acidosis]
- decline in visual acuity, color blindness, blurred vision/defect in the visual field [optic neuropathy]
- breathing difficulty, generalized hot flush, hives [shock, anaphylaxis]
- fever, cough/phlegm, breathing difficulty [interstitial pneumonia]

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 reach of children. Store in a light shielding condition at room temperature (1 to 30 degrees Celsius), away from moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.