

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

Internal

Revised: 02/2015

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: Sawacillin Capsules 125

Active ingredient: Amoxicillin hydrate

Dosage form: brown/white capsule, (length: 15.7mm)

Print on wrapping: (Face) サワシリン 125mg, 125mg, (Back) サワシリン 125mg, アモキシシリン (Amoxicillin), 抗生物質, house-mark



Effects of this medicine

This medicine is a penicillin antibiotic and inhibits cell wall synthesis of bacteria etc. to suppress bacterial growth, thus showing bactericidal antimicrobial action.

It is usually used for the treatment of a wide range of infections such as respiratory infection, skin infection, otorhinological infection, urinary tract infection and odontogenic infection (oral and dental infection).

Also used, in combination with other drugs, for eradication of *Helicobacter pylori* infection of the stomach in gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, or after endoscopic therapy for early-stage gastric carcinoma, and *Helicobacter pylori*-associated gastritis.

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 infectious mononucleosis.
- 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 >>
- Common infection (except for *Helicobacter pylori* infection): In general, for adults, take 2 capsules [250 mg (titer) of the active ingredient] three or four times a day. For children, take 20 to 40 mg (titer)/kg body weight of the active ingredient a day in three or four divided doses. Although the dosage should be adjusted according to your age and symptom, it should not exceed 90 mg (titer)/kg body weight a day.
Helicobacter pylori infection and *Helicobacter pylori*-associated gastritis: In general, for adults, take 6 capsules [750 mg (titer) of the active ingredient] with other two drugs [either clarithromycin or metronidazole and proton-pump inhibitor (any one of lansoprazole, omeprazole, sodium rabeprazole, esomeprazole, or vonoprazan)] at a time, twice a day, for seven days. Each capsule of this medicine contains 125 mg (titer) of the active ingredient. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. However, 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, fever, diarrhea, loose stool, nausea, vomiting, loss of appetite, stomachache and taste abnormality. 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.

- discomfort, breathing difficulty, hives [shock, anaphylaxis]
- fever, headache, erythema/blister/pustule [toxic epidermal necrosis, muco-cutaneo-ocular syndrome, erythema multiform, acute generalized exanthematous pustulosis, erythroderma(dermatitis exfoliative)]
- general malaise, loss of appetite, yellowing of the skin or white of the eyes [jaundice]
- decreased urine output, swelling, general malaise [renal failure acute]
- dry cough, breathing difficulty, fever [interstitial pneumonia, eosinophilic 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 the reach of infants and 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.