

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

Internal

Published: 09/2017

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: PASETOCIN Capsules 125

Active ingredient: Amoxicillin hydrate

Dosage form: pale blue/white capsule, (length: 16.0 mm)

Print on wrapping: KH806 パセトシシ 125 mg



Effects of this medicine

This medicine is a penicillin antibiotic and inhibits cell wall synthesis, thus sterilizing the bacteria themselves which has caused inflammation (fever, pain or swelling).

It is usually used for the treatment of a wide range of infections such as skin/respiratory/urinary/otolaryngology/dental and ophthalmologic infections. Also used for, in combination with other medicines, eradication of *Helicobacter pylori* infection in gastric ulcer, duodenal ulcer, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, idiopathic thrombocytopenic purpura or stomach after endoscopic treatment of early gastric cancer, 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, your parents or your brothers/sisters have allergic tendency (bronchial asthma, rash, hives, etc.) or renal disorder.
- 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))
- Infection (except for *Helicobacter pylori* infection): In general, for adults, take 2 capsules [250 mg (titer) of the active ingredient] at a time, 3 or 4 times a day. For children, take 20 to 40 mg (titer) of the active ingredient /kg of body weight in 3 or 4 divided doses a day. Although the dosage should be adjusted according to your age and symptom, for children, it should not exceed 90 mg (titer) /kg of 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 medicines [either clarithromycin or metronidazole and proton-pump inhibitor (any one of lansoprazole, omeprazole, rabeprazole sodium, esomeprazole or vonoprazan)] at a time, twice a day, for 7 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. 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

- During eradication therapy for *Helicobacter pylori*, it is important that you continue taking the medicine as directed by your doctor. Furthermore, please also read the medical information sheets "Kusuri-no-Shiori" for the other 2 medicines to be taken concomitantly (clarithromycin or metronidazole and a proton-pump inhibitor [lansoprazole, omeprazole, rabeprazole sodium, esomeprazole or vonoprazan]).

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, fever, loss of appetite, diarrhea, loose stool, nausea/vomiting, abdominal pain, dyspepsia, taste abnormality, stomatitis, glossitis, constipation and esophagitis. 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.

- dyspnea, generalized flushing, hives [shock, anaphylaxis]
- fever, headache, arthralgia, dermal or mucosal erythema/blisters/pustule [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiform, acute generalized exanthematous pustulosis, erythroderma (dermatitis exfoliativa)]
- generalized malaise, loss of appetite, yellowness in skin or in white part of eye [jaundice]
- decrease of urine output, edema, headache [nephropathy]

- abdominal pain, diarrhea, bloody stool [pseudomembranous colitis, hemorrhagic colitis]
- dry cough, shortness of breath, fever [interstitial pneumonia, eosinophilic pneumonia]
- inability to bend the neck forward due to rigidity of the nape of the neck, fever, headache [aseptic meningitis]

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.