

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

Internal

Revised: 05/2017

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:ASACOL tablets 400mg

Active ingredient:Mesalazine

Dosage form:reddish brown to brown tablet, major axis: 14.7 mm, minor axis: 5.9 mm, thickness: 6.5 mm

Imprint or print on wrapping:アサコール錠 400mg, ZP65



Effects of this medicine

This medicine releases its active ingredient in the large intestine. It eliminates activated oxygen released from inflammatory cells and inhibits the synthesis of leukotriene B₄. It suppresses inflammation in the large intestine, and consequently improves abdominal pain and hematochezia.

It is usually used in the treatment of ulcerative colitis.

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: renal or hepatic 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))
- In general, for adults, take 2 tablets (800 mg of the active ingredient) at a time, 3 times daily, after meal. In remission stage of the disease, however, you may be instructed to take six tablets (2,400 mg of the active ingredient) at a time, once daily, as necessary. In active stage of the disease, take 3 tablets (1,200 mg of the active ingredient) at a time, 3 times daily, after meal. The dosage may be decreased according to the patient's condition. Strictly follow the instructions.
- Swallow the tablet without chewing because the medicine is designed to dissolve and release the active ingredient in the large intestine.
- 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 not 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

- Sometimes you will find broken pieces of the tablet (brown) in your stool, however, it is the coating agent and has no problem.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, diarrhea, abdominal bloating, nausea, headache, exacerbation of ulcerative colitis, colonic polyp, liver function abnormality (including liver disorder) and fever. 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, fever, throat pain, nasal bleeding, gum bleeding [myelosuppression, aplastic anemia, pancytopenia, agranulocytosis, leukopenia, neutropenia, thrombocytopenia]
- chest pain, palpitation, shortness of breath, fever [myocarditis, pericarditis, pleurisy]
- breathing difficulty, chest pain, dry cough [interstitial lung disease]
- severe pain in the upper abdomen or lower back, fever, nausea [pancreatitis]
- decreased urine output, edema, general malaise [interstitial nephritis, nephrotic syndrome, renal failure]
- loss of appetite, general malaise, yellowing in the skin or conjunctiva ocular [hepatitis, liver dysfunction, jaundice]

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 the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- Do not store the remainder and discard it.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.