

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

Internal

Revised: 02/2019

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:Imuran Tablets 50mg [Crohn's disease, ulcerative colitis, Autoimmune hepatitis]

Active ingredient:Azathioprine

Dosage form:pale yellowish white tablet, diameter: 7.4mm, thickness: 3.0mm

Print on wrapping:(back) Imuran, イムラン 50mg, GXCH1



Effects of this medicine

This medicine shows immunosuppressive effects by inhibiting nucleic acid synthesis. It enables dose reduction of steroid used in combination while suppressing symptom's recurrence of Crohn's disease, keeps the remission duration longer when remitting disease condition due to steroid use, and suppresses symptoms caused by autoimmune hepatitis.

It is usually used for remission induction and remission maintenance of steroid dependence Crohn's disease, remission maintenance of steroid dependence ulcerative colitis and treatment of autoimmune hepatitis.

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 your white blood cell count is $3,000/\text{mm}^3$ and less.
If you have: bone marrow dysfunction, infections, hemorrhagic diathesis, hepatic dysfunction, renal failure or varicella.
- 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 and children, take 1 to 2 mg of the active ingredient per kg of the body weight (commonly, for adults, 50 to 100 mg) as a daily dose. This preparation contains 50 mg of the active ingredient in a tablet. 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

- To avoid risk of skin cancer due to exposing to sunlight and ultraviolet (UV) rays, wear clothing that filters out UV rays and apply sunscreen to avoid sunlight and UV rays.
- This medicine may cause serious adverse reactions such as decreased bone marrow function and liver dysfunction. The blood/liver/renal function tests may be performed every 1 to 2 weeks at the beginning of the medication as a guide and then frequently performed. You should receive the test on the designated date.
- If you or your partner have a possibility of becoming pregnant, consult with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, vasculitis, renal dysfunction, general malaise, myalgia, joint pain, fever, chilliness, dizziness and diarrhea. 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.

- anemic symptoms, hemorrhagic symptoms, fever [aplastic anaemia, blood disorder such as pancytopenia]
- chilliness, shivering, dizziness on standing up [shock-like symptoms]
- general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic dysfunction, jaundice]
- fever, dry cough, breathing difficulty [[interstitial pneumonia]
- disturbance of consciousness, paralytic symptoms, speech impediment [progressive multifocal leukoencephalopathy]

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 light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.