

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

Internal
Revised: 06/2020

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: Urinorm Tablets 25mg

Active ingredient: Benzbromarone

Dosage form: white tablet with split line, diameter: 6.5 mm, thickness: 2.1 mm

Print on wrapping: ユリノーム錠 25mg, TO-082 25

**Effects of this medicine**

This medicine increases excretion of uric acid in the urine by inhibiting reabsorption of uric acid in renal tubules. It consequently improves hyperuricemia.

It is usually used to treat gout, hypertension accompanied by hyperuricemia.

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: liver damage, kidney stones, renal dysfunction.
- If you are pregnant, possibly 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 gout: In general, for adults, take 1 or 2 tablets (25 or 50 mg of the active ingredient) at a time, once a day. Then, as maintenance dose, take 2 tablets (50 mg) at a time, once to 3 times a day.
For hypertension accompanied by hyperuricemia: In general, for adults, take 2 tablets (50 mg of the active ingredient) at a time, once to 3 times a day.
In any case, the dosage should be adjusted according to the disease, age and symptoms. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. 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

- The periodical liver function test is carried out for the first six months from a medicine start. The liver function test may be performed on a regular basis on and after the sixth month. Do not miss appointments with your doctor.
- If your urine has acidity, you are likely to develop symptoms such as uric acid stone, consequential hematuria, renal colic. For prevention, drink a lot of water to increase urinary volume and to alkalize it.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include discomfort in stomach, gastrointestinal disorder, itchiness, rash 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.

- loss of appetite, malaise, jaundice (yellowness in skin or in eyes) [serious liver damage]

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. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.