

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

Internal

Revised: 08/2022

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: URECE Tablets 1mg

Active ingredient: Dotinurad

Dosage form: white to pale yellowish white tablet with split line, diameter: approx. 8.0 mm, thickness: approx. 3.8 mm

Imprint or print on wrapping: ユリス錠 1mg, FY322, 痛風・高尿酸血症のお薬です, URECE 1mg



Effects of this medicine

This medicine increases excretion of uric acid in the urine by inhibiting reabsorption of uric acid in kidney, and it consequently reduce blood uric acid level.

It is usually used to treat gout and hyperuricemia.

This medicine does not suppress pain and inflammation when a gouty attack (gouty arthritis) occurs.

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: urinary stone, renal dysfunction, liver dysfunction.
- 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, start with 0.5 mg of the active ingredient at a time, once a day. The dosage may be gradually increased according to your blood uric acid level as needed. It may be increased to 1 mg at a time, once a day after 2 weeks, and then 2 mg at a time, once a day as maintenance dose after 6 weeks. The dosage may be adjusted according to your condition. However, it should not exceed 4 mg at a time, once a day. This preparation contains 1 mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you experience gout attack (pain) while taking this medicine, do not adjust your dose or stop taking this medicine. Consult with your doctor.
- If you miss a dose, take a dose as soon as possible when you remember that you missed a dose. 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

- If your urine has acidity, you are likely to develop symptoms such as urinary stone, consequential hematuria, renal colic. For prevention, drink plenty of water to increase urinary volume and alkalize urine.
- Follow your doctor's instructions and have regular clinical examinations.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include gouty arthritis, arthritis and discomfort in limbs. 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.

No pertinent entries.

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. If you do not know how to dispose of it, please consult the pharmacy or medical institution where you received it. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.