

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

Internal

Revised: 02/2022

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: URITOS OD Tablets 0.1mg

Active ingredient: Imidafenacin

Dosage form: white tablet, diameter: 7.6mm, 4.1mm thick

Imprint or print on wrapping: (face)ウリス OD 錠 0.1mg 過活動膀胱治療剤 KP-121
(reverse side)URITOS ODTab.0.1mg ウリス OD 錠 0.1mg 過活動膀胱治療剤 Kyorin



Effects of this medicine

This medicine helps control overactive contraction of bladder smooth muscle which is uncontrollable by oneself, so to facilitate holding urine in the bladder, with the antagonistic action of this medicine to muscarinic receptor of the bladder.

It is usually used to treat urinary urgency, frequent urination and urgency urinary incontinence due to overactive bladder.

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 retention, paralytic ileus (intestinal obstruction), decline of gastrointestinal motor ability/tension (includes gastric/bowel atony), glaucoma, myasthenia gravis or heart disease.
- 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 1 tablet (0.1 mg of the active ingredient) at a time, twice a day after breakfast/supper. If the efficacy was not enough, increase dosage up to 2 tablets (0.2 mg of the active ingredient) at a time, twice a day. Strictly follow the instructions of your doctor and pharmacist.
- The medicine can be taken by swallowing with saliva alone, after the tablets soaked with saliva on the tongue are disintegrated into pieces. The medicine can be, naturally, taken with water.
- The medicine should not be taken without water at the recumbent position.
- If you miss a dose, take a dose when you remember. However, if it is almost time for the next dose, skip the missed dose and follow 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 medicine may cause disorders in vision adjustment (foggy/blurred vision), dizziness and drowsiness; pay close attention when you drive a car, work at heights or operate dangerous machinery while you take the medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dry mouth, thirsty mouth, constipation, residual urine, foggy vision, photophobia (sensitive to bright light), stomach and abdominal discomfort, drowsiness, headache, dysuria, itch and rash. 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.

- nausea, eye pain with headache, failing eyesight [acute glaucoma]
- difficult to urinate, impossible to urinate [urinary retention]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [liver dysfunction]

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 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.