

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

Internal

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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:** Tolvaptan OD Tablets 7.5mg "TE"

**Active ingredient:** Tolvaptan

**Dosage form:** light blue tablet with split line, major axis: 7.8 mm, minor axis: 4.4 mm, thickness: 3.1 mm

**Imprint or print on wrapping:** (face) トルバプタン OD, 7.5mg「TE」, 利尿薬  
(back) トルバプタン OD「TE」, 7.5mg



**Effects of this medicine**

This medicine acts on the kidneys and resolves swelling of the body by increasing the urine output and removing unnecessary fluids.

It is usually used for the treatment of fluid retention in liver cirrhosis in combination with other diuretics when the other diuretics alone do not show sufficient effect.

**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 are unable to sense thirst or have impaired fluid intake, anuria, hepatic encephalopathy, or hypernatremia.
- 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))
- In general, for adults, take 1 tablet (7.5 mg of the active ingredient) at a time, once a day. In order to avoid nocturnal urination, it is desirable to take the medicine in the morning. Your doctor may decide to start the medicine at half dose (3.75 mg) or to later reduce the dose to half according to your symptoms. Strictly follow the instructions.
- You can take this medicine without water. Soak the tablet with saliva on your tongue and crush it lightly with your tongue, then swallow it with saliva. You can also take it with water or warm water as you do an ordinary tablet. Do not take the tablet without water when you are lying down.
- 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**

- If you feel thirst, drink an appropriate amount of water to prevent dehydration but be careful not to drink an excessive amount.
- Pay attention that this medicine increases both urine volume and urination frequency.
- If you have a possibility of pregnancy, avoid pregnancy while taking this medicine. Consult with your doctor immediately if you become pregnant while taking this medicine.
- This medicine may cause dizziness. Pay close attention to falling, driving a car, working at heights, or operating dangerous machinery.
- Avoid taking this medicine with grapefruit juice, since it may enhance the effects of this medicine.
- Avoid taking this medicine with any food containing St. John's wort, since it may reduce the effects of this medicine.
- As frequent serum sodium concentration measurements are necessary while taking this medicine, follow the instructions of your doctor.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include headache, dizziness, thirst, constipation, frequent urination, excessive urination, fatigue and excessive fluid intake. 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.**

- general malaise, decreased urine output, swelling [renal failure]
- localized pain, chest pain, breathing difficulty [thromboembolism]

- mental confusion and hyperventilation, dehydration symptoms such as thirst, decreased consciousness [hyponatremia]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [acute hepatic failure, liver dysfunction]
- dizziness on standing up, hives, respiratory distress [shock, anaphylaxis]

**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 them, consult with your dispensing pharmacy or medical institution. Do not give this medicine to others.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.