

# 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:**SILODOSIN OD TABLETS 2mg 「OHARA」

**Active ingredient:**Silodosin

**Dosage form:**pale yellowish red tablet, diameter : 6.5mm, thickness : 3.0mm

**Print on wrapping:**シロドシン OD2mg「オーハラ」、排尿障害改善薬、口腔内崩壊錠、SilodosinOD2mg「OHARA」



## Effects of this medicine

This medicine lowers internal pressure of urethra by blocking  $\alpha_{1A}$ -receptors in urethra and prostate gland, and consequently improves urination disorder associated with prostatic hypertrophy. It is usually used to treat urination disorder associated with prostatic hypertrophy.

## 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 orthostatic hypotension, hepatic dysfunction or renal dysfunction.
- 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 2 tablets (4 mg of the active ingredient) at a time, twice a day, after breakfast and supper. The dosage may be decreased according to the symptoms. Strictly follow the instructions.
- Since the tablet dissolves with saliva when you place it on your tongue, you can take it without water. You can also take it with water as you do for an ordinary tablet. However, do not take the tablet without water when you are lying down.
- If you miss a 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

- This medicine may cause dizziness. Pay close attention to engaging in dangerous activities such as working at heights or driving a car.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include ejaculation disorder (retrograde ejaculation), dry mouth, diarrhea, loose stools, dizziness on standing up, nasal congestion, dizziness, light-headedness and headache. 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.**

- decreased blood pressure, fainting, loss of consciousness [faint, loss of consciousness]
- general malaise, loss of appetite, yellowing of skin and the white of eyes [hepatic dysfunction, jaundice]

**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. Ask the pharmacist or medical institution how to discard them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

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