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

Internal

Revised: 03/2016

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: TAMSULOSIN HYDROCHLORIDE CAPSULES 0.2mg

Active ingredient: Tamsulosin hydrochloride

Dosage form: very light red/white opaque capsule, major axis: 14.2 mm, minor axis: 5.3

mm

Print on wrapping:タムスロシン塩酸塩 0.2mg「オーハラ」, 0.2mg, 前立腺肥大症の排尿障害改善剤です, Tamsulosin Hydrochloride 0.2mg「OHARA」,

OH-354, タムスロシン塩酸塩



Effects of this medicine

This medicine relaxes urinary tract smooth muscle by blocking α_1 receptors in the urethra and prostate. It consequently reduces urethral pressure to help urination.

It is usually used to treat urination disorder accompanied with prostatic hyperplasia.

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 1 capsule (0.2 mg of the active ingredient) at a time, once a day after a meal. The dosage may be adjusted according to your age and symptoms. Strictly follow the instructions.
- •If you miss a dose, take the missed dose as soon as possible. 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

•This medicine may cause dizziness, etc. Pay close attention when performing dangerous operations such as working at heights or driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness, stomach discomfort, itching, rash, hives and erythema multiforme. 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.

- •faint, loss of consciousness [faint, loss of consciousness]
- general malaise, loss of appetite, vellowing of the 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 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.

SIE3