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

Internal

Revised: 09/2025

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: VALSARTAN TABLETS 80mg [OHARA]

Active ingredient: Valsartan

Dosage form: white tablet, diameter: 8.6 mm, thickness: 3.7 mm

Imprint or print on wrapping:バルサルタン 80 mg「オーハラ」, 血圧降下薬,

Valsartan 80 mg 「OHARA」, 80 mg



Effects of this medicine

This medicine lowers blood pressure in patients with hypertension by binding to angiotensin II receptors that are produced in the body, thereby blocking vasoconstriction by angiotensin II, which has vasopressor action. It is usually used to treat hypertension.

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 diabetes mellitus, renal disorder or hyperkalemia.

If you are receiving hemodialysis.

If you are on a regimen of low-salt diet.

If you have been scheduled for surgery.

- · If you are pregnant or breastfeeding, possibly pregnant.
- •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))

• For adults: In general, take 40 to 80 mg as the active ingredient at a time, once a day. The dosage may be adjusted according to age/symptoms, but may be increased up to 160 mg a day.

<u>For children over 6 years old</u>: In general, for children weighing less than 35 kg, take 20 mg as the active ingredient at a time, once a day. For children weighing more than 35 kg, take 40 mg at a time, once a day. The dosage may be adjusted according to age/weight/symptoms. However, the maximum daily dose for children weighing less than 35 kg is 40 mg.

- This medicine contains 80 mg as the active ingredient in a tablet. Strictly follow the instructions.
- •If you miss a dose, take the missed dose as soon as possible. However, if you are to take the next dose within 8 hours, 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

- Decreased blood pressure may result in dizziness or light headedness. Pay attention when working at heights, or operating dangerous machinery, such as driving a car.
- This medicine cannot be used by pregnant and possible pregnant women. If you become pregnant or think you may be pregnant while taking this medicine, consult your doctor immediately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, hives, erythema, photosensitivity, dizziness, headache, hypotension, palpitation, nausea, abdominal pain, cough (dry cough), malaise and edema. 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.

- swelling of face, lips, throat or tongue, breathing difficulty, abdominal pain, diarrhea [angioedema]
- ·loss of appetite, general malaise, yellow discoloration of the skin and the white of eyes [hepatitis]
- ·decreased urine output, edema of limbs, loss of appetite [renal failure]
- ·loss of consciousness, vomiting, feeling cold [shock, syncope, loss of consciousness]
- •muscle weakness, numbness of limbs or lips, paralysis of limbs [hyperkalemia]

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 discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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