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

Internal Published: 06/2014

| 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 160mg [OHARA]  |
| Active ingredient: Valsartan   |
| Dosage form:white tablet, major axis: 14.6 mm, minor axis: 5.8 mm, thickness: 5.7 mm   |
| Print on wrapping:バルサルタン 160 mg「オーハラ」,血圧降下薬, Valsartan 160 mg  |
| [OHARA], 160 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.  |
| 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 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.  |
|  |
| <ul> <li>If you are pregnant, possibly pregnant or breastfeeding.</li> <li>If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal</li> </ul>  |
|  |
| 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>>  |
| • <u>For adults</u> : 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.  |
| For children over 6 years old: 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 160 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.   |
| Dessible scheme reactions to this marile is  |
| 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 [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]   |
| 1 / 2  |

| 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.

SIE①