

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:AMVALO COMBINATION TABLETS 「OHARA」

Active ingredient:Valsartan

Amlodipine besilate

Dosage form:yellowish white tablet, diameter: 8.6 mm, thickness: 3.9 mm

Imprint or print on wrapping:アムバロ配合錠「オーハラ」, バルサルタン 80mg, アムロジピン 5mg, 血圧降下薬, AmvaloCombinationTab「OHARA」



Effects of this medicine

This medicine blocks the vasoconstrictive effects of angiotensin II produced in the body, and dilates peripheral blood vessel to lower blood pressure in patients with hypertension.

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, liver disorder, hyperkalemia.
- If you are on dialysis or low-salt diet.
- If you are 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))
- In general, for adults, take 1 tablet at a time, once a day. 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 not 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

- The medicine may cause dizziness or light-headedness since the blood pressure is decreased. Pay attention when you perform dangerous operations such as working at heights or driving a car.
- Avoid taking the medicine with grapefruit juice, since it may intensify medicinal effects.
- 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 dizziness and rash. 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/tongue, breathing difficulty, abdominal pain, diarrhea [angioedema]
- loss of appetite, general malaise, yellowing of the skin and the white of eyes [fulminant hepatitis, hepatitis, liver dysfunction, jaundice]
- decreased urine output, edema, loss of appetite [renal failure]
- loss of consciousness, vomiting, cold feeling [shock, syncope, loss of consciousness]
- numbness of lips/limbs, muscle weakness, 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.

SIE③