

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

Internal

Revised: 01/2016

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:AMLODIPINE TABLETS 5mg 「OHARA」

Active ingredient:Amlodipine besilate

Dosage form:white tablet with a split line (diameter : 8.1 mm, thickness: 3.4 mm)

Print on wrapping:アムロジピン 5mg「オーハラ」、アムロジピン, 5mg, Amlodipine 5mg 「OHARA」、アムロジピン「オーハラ」、高血圧、狭心症のお薬です



Effects of this medicine

This medicine enlarges the peripheral arteries and the coronary vessels, decreases blood pressure by reducing influx of calcium ion into cells, and consequently prevents or relieves episode of angina.

It is usually used for the treatment of hypertension and angina pectoris.

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 hypotension, hepatic or renal dysfunction.
- If you are pregnant, possibly pregnant or breastfeeding.
- 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 the treatment of hypertension: In general, for adults, take 1/2 to 1 tablet (2.5 to 5 mg of amlodipine) at a time, once daily. The dosage may be adjusted according to the symptoms, however, if the effect is insufficient, the dosage may be increased up to 2 tablets (10 mg of amlodipine) at a time, once daily. For children over the age of 6 years, take 1/2 tablet (2.5mg of amlodipine) at a time once a day. The dosage may be adjusted according to the patient's age, body weight and symptom. However, the daily dose is up to 1 tablet (5mg).
For the treatment of angina pectoris: In general, for adults, take 1 tablet (5 mg of amlodipine) at a time, once daily. The dosage may be adjusted according to the symptoms.
Strictly follow the instructions in any case.
- If you miss a dose (For hypertension), there is no need to take a dose on that day, and continue your regular dosing schedule from the next day. (For angina pectoris), take a dose as soon as possible when you remembered that you missed a dose. 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

- The medicine may cause dizziness or lightheadedness due to the antihypertensive action. Pay close attention when you work at heights, drive a car or operate dangerous machinery.
Grapefruit juice may intensify the therapeutic effects of the medicine. Do not take the medicine with grapefruit juice.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include edema, glow (feeling hot, facial flash), palpitation, dizziness, lightheadedness, headache, headache dull, rash, itch, hives, photosensitivity, erythema multiforme, vasculitis, angioedema (swelling of eyelids or lips, breathing difficulty) and gingival overgrowth. 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.

- general malaise, loss of appetite, yellowness in the skin or white of the eyes [fulminant hepatitis, hepatic dysfunction, jaundice]
- sore throat, headache, nose bleeding, gum bleeding [agranulocytosis, leukocytopenia, thrombocytopenia]
- faint, dizziness, bradycardia [atrioventricular block]
- muscle pain of limbs, stiffness, numbness [rhabdomyolysis]

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 the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- Do not store the remainder and ask your pharmacist or medical institution how to discard it.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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