

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: Norvasc Tablets 2.5mg

Active ingredient: Amlodipine besilate

Dosage form: white tablet, diameter: 6.0 mm, thickness: 3.0 mm

Print on wrapping: ノルバスク 2.5mg, Norvasc 2.5mg, 高血圧症 狭心症の薬です



Effects of this medicine

This medicine is a calcium channel blocker to reduce the movement of calcium into the cells of the heart and blood vessels. As a result, it relaxes coronary and peripheral blood vessels to lower blood pressure and prevent an angina attack.

It is usually used to treat hypertension and angina.

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: low blood pressure, liver dysfunction or kidney 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 Adults:

For treatment of hypertension: In general, take 1 to 2 tablets (2.5 to 5 mg of amlodipine) at a time, once a day. The dosage may be adjusted according to the symptoms. If it is not effective enough, then increase the dose up to maximum of 4 tablets (10 mg) at a time, once a day.

For treatment of angina: In general, take 2 tablets (5 mg of amlodipine) at a time, once a day. The dosage may be adjusted according to the symptoms.

For Children:

For treatment of hypertension: In general, for children over the age of 6 years, take 1 tablet (2.5 mg of amlodipine) at a time, once a day. The dosage may be adjusted according to the age, body weight or symptoms. However, the maximum daily dose is 2 tablets (5 mg).

In any case, strictly follow the instructions.

- (For treatment of hypertension) If you miss a dose, follow your regular dosing schedule from the next day. (For treatment of angina) If you miss a dose and remember it within one day, take the missed dose as soon as possible. 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 and light headedness due to lowered blood pressure. Pay attention when you drive a car, work at heights or operate dangerous machines.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include glow (heat sensation, facial hot flush, etc.), dizziness/light headedness, headache/dull headache, palpitation, edema, rash, itch, hives, solar sensitiveness, erythema multiform, vasculitis, angioedema and gingival hyperplasia caused by continuous use. 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.

- nausea/vomiting, general malaise, yellowing of the skin and the white of eyes [fulminant hepatitis, liver dysfunction, jaundice]
- sore throat, fever, bleeding tendency (gum or nose bleeding) [agranulocytosis, leukopenia, thrombocytopenia]
- bradycardia, dizziness, syncope [atrioventricular block]
- muscle pain, lassitude, reddish brown urine [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 out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, ask the pharmacist or the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.