

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

Internal

Revised: 01/2017

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 "AMEL"

**Active ingredient:** Amlodipine besilate

**Dosage form:** white tablet, diameter, diameter: 8.2 mm, thickness: 3.1 mm

**Print on wrapping:** アムロジピン 5mg「アメル」、5、KW061

Amlodipine 5mg《AMEL》、アムロジピン「アメル」、5mg



## Effects of this medicine

This medicine is a calcium channel blocker which reduces calcium inflow into cells to relax coronary artery and peripheral blood vessels to lower blood pressure, and relieve frequency of angina attacks. It is usually used to treat 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, 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))
- **Hypertension:** In general, for adults, take 0.5 to 1 tablet (2.5 to 5 mg of amlodipine) at a time, once a day. The dosage may be adjusted according to the symptoms. If the dose seems to be insufficient, the dosage will be increased to 2 tablets (10 mg) at a time, once a day.  
In general, for children 6 years or over, take 0.5 tablets (2.5 mg of amlodipine) at a time, once a day. The dosage may be adjusted according to the age, body weight or symptoms. The maximum daily dose is 1 tablet (5 mg).
- **Angina pectoris:** In general, for adults, take 1 tablet (5 mg of amlodipine) at a time, once a day.  
The dosage may be adjusted according to the symptoms.  
In any case, strictly follow the instructions.
- (For hypertension) If you miss a dose, skip the missed dose and follow your regular dosing schedule the following day. (For angina pectoris) If you miss a dose and notice 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 or light headedness due to a fall of blood pressure. Pay close attention when driving a car, working at heights or operating dangerous machinery.
- Avoid taking grapefruit juice with this medicine, since it may intensify the effects of this medicine.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include glow (heat sensation, hot flush, etc.), dizziness/light headedness, headache/dull headache, palpitation, edema, rash, itching, hives, photosensitivity, erythema multiform, vasculitis, angioedema (swelling of the eyelids and lips, respiratory distress) and gingival hyperplasia due to chronic use of this medicine. 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/vomit, general malaise, yellowing of the skin and the white of eyes [fulminant hepatitis, liver dysfunction, jaundice]
- sore throat, fever, bleeding tendency (gum/nose bleeding, etc.) [agranulocytosis, leukopenia, thrombocytopenia]
- bradycardia, dizziness, syncope [atrioventricular block]
- muscle pain, lassitude, red-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 light, heat and moisture.
- Discard the remainder. Do not store them. Seek advice of your pharmacy or medical institution about proper

disposal of the unused medicines.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.