

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

Internal

Revised: 11/2023

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: Caduet combination Tablets 2Ban

Active ingredient: Amlodipine besilate

Atorvastatin calcium hydrate

Dosage form: white tablet, diameter: 6.4 mm, thickness: 2.9 mm

Imprint or print on wrapping: Caduet 2Ban, アムロジピン 2.5mg・アトルバスタチン 10mg, CDT 251, カデュエット2番, VIATRIS, アムロジピン2.5mg, アトルバスタチン 10mg, pfizer



Effects of this medicine

This medicine relaxes the coronary and peripheral vessels by decreasing the influx of calcium into the cell. As a result, it lowers blood pressure and prevents an angina attack. Also, it lowers the blood cholesterol by inhibiting hepatic cholesterol synthesis.

It is usually used to treat hypertension or angina pectoris complicated by hypercholesterolemia or familial hypercholesterolemia.

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: decreased hepatic metabolism, decreased blood pressure, diabetes mellitus, hypothyroidism, hereditary muscular disease (e.g., muscular dystrophy) or family history of it, a history of drug-induced muscular disorder, alcoholism, myasthenia gravis or a history of it, liver dysfunction 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 treatment of hypertension: In general, for adults, take 2.5 to 5 mg of amlodipine at a time, once a day, to be adjusted according to the symptoms. If it is not effective enough, the dosage may be increased up to 10 mg of amlodipine at a time, once a day.
For treatment of angina pectoris: In general, for adults, take 5 mg of amlodipine at a time, once a day, to be adjusted according to the symptoms.
For treatment of hypercholesterolemia: In general, for adults, take 10 mg of atorvastatin at a time, once a day, to be adjusted according to the age or symptoms. For severe symptoms, the dosage may be increased up to 20 mg of atorvastatin a day.
For treatment of familial hypercholesterolemia: In general, for adults, take 10 mg of atorvastatin at a time, once a day, to be adjusted according to the age or symptoms. For severe symptoms, the dosage may be increased up to 40 mg of atorvastatin a day.
This preparation contains 2.5 mg of amlodipine and 10 mg of atorvastatin in a tablet. In any case, strictly follow the instructions.
- If you miss a dose, 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

- Dizziness or light headedness may occur associated with decreased blood pressure. Pay close attention to driving a car, working at heights or operating dangerous machinery.
- Strictly follow the instructions on dietary/exercise therapy.
- Avoid taking grapefruit juice with this medicine, since it may intensify the therapeutic effects of this medicine.
- Liver function test is performed at least once within 12 weeks and periodically thereafter (e.g., once in a half year) after the start of taking this medicine or the dose increase of this medicine.
- Blood test, renal function test, etc. are performed periodically while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include palpitation, liver dysfunction, headache, dizziness/light headedness, itch, hot flush (feeling hot, facial flushing, etc.), edema, stomach discomfort, insomnia and constipation.

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, hepatitis, liver dysfunction, jaundice]
- fever, sore throat, nose bleeding/subcutaneous bleeding [agranulocytosis, decreased white blood cell, pancytopenia, thrombocytopenia]
- dyspnea, hives, swelling around the eyes and lips [hypersensitivity]
- bradycardia, shortness of breath, dizziness [atrioventricular block]
- muscle pain, weakness, reddish brown urine [rhabdomyolysis, myopathy, immune-mediated necrotizing myopathy]

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 and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, 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.