

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

Internal

Revised: 06/2013

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: Adalat-CR Tablets 40mg**

**Active ingredient:** Nifedipine

**Dosage form:** reddish brown tablet, diameter: 8.1 mm, thickness: 5.0 mm

**Print on wrapping:** front/アダラート CR40, 40, AO40

back/Adalat-CR40, アダラート CR40, 40



**Effects of this medicine**

This medicine suppresses calcium ion influx into cells which causes contraction of the heart and vessels, to dilate the coronary vessel and to decrease total peripheral vascular resistance. It consequently shows antihypertensive effects and antianginal effects.

It is usually used in 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: cardiogenic shock, aortic valve stenosis, mitral valve stenosis, pulmonary hypertension, excessive hypotension, renal dysfunction, hepatic dysfunction or congestive heart failure.  
If you are on hemodialysis.
- 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))
- General dosage regimen:  
For hypertension: In general, for adults, start taking 10 to 20 mg of the active ingredient at a time, once daily. The dosage may be gradually increased as necessary to take 20 to 40 mg at a time, once daily. In case of uncontrolled with 40 mg once daily, the dosage may be increased to 40 mg at a time, twice a day.  
For renal parenchymal hypertension and renovascular hypertension: In general, for adults, start taking 10 to 20 mg of the active ingredient at a time, once daily. The dosage may be gradually increased as necessary to take 20 to 40 mg at a time, once daily.  
For angina pectoris and variant angina pectoris: In general, for adults, take 40 mg of the active ingredient at a time, once daily. The dosage may be adjusted according to the symptoms, however, the maximum daily dose is limited to 60 mg.  
This preparation contains 40 mg of the active ingredient in a tablet. Strictly follow the instructions.
- Swallow the medicine without splitting or chewing since it is a sustained-release tablet. If you chew and swallow it, the blood concentration will increase and it may cause adverse reactions such as headache or facial flush.
- If you miss a dose, take a 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 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 the medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

- The medicine may cause dizziness and lightheadedness since it causes hypotension. Be careful when you work at heights, drive a car or operate dangerous machinery.
- Grapefruit juice intensifies 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 headache, headache dull, facial flush, facial hot flush, palpitation, constipation, edema, tachycardia, jaundice, chest pain, upper abdominal pain, rash, itch, photosensitivity, purpura, gingival hyperplasia, anemia, breathing difficulty and gynecomastia. 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 redness, skin exfoliation, fever, general malaise [erythroderma (exfoliative dermatitis)]
- headache, fever, throat pain, muscle pain [agranulocytosis]
- nasal bleeding, blue bruise, bleeding tendency, difficulty in stopping bleeding [thrombocytopenia]

- general malaise, yellowing in the skin and the white of the eye, loss of appetite [hepatic dysfunction, jaundice]
- decreased conscious, disturbed thinking, decreased judgement [conscious disorder]

**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. Ask the pharmacy or medical institutions how to discard.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.