

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

612140443

Revised: 02/2011

Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.

In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.

Brand name : Renivace Tablets-2.5

Active ingredient : Enalapril maleate

Dosage form : pale pink tablet (φ : 5.1 mm, thickness: 1.7 mm)

Printings on wrapping : レニベース 2.5, 湿気に注意



Effects of this medicine

This medicine suppresses production of angiotensin II, which is a hypertensive substance, by inhibiting angiotensin-converting enzyme, and consequently decreases blood pressure. It also improves hemodynamics and raises cardiac output by decreasing peripheral vascular resistance, and consequently improves cardiac hypertrophy.

It is usually used in the treatment of various hypertension and chronic heart failure (mild to moderate).

Before using this medicine, tell your doctor/pharmacist

- If you ever experienced any allergic reaction (itch, rash, etc.) to any medicine.
If you have a history of angioedema.
- If you are a patient with renal disorder or cerebrovascular disorder (cerebral stroke etc.).
If you are receiving apheresis or hemodialysis.
- If you are on a sodium restriction diet.
- If you are pregnant or breastfeeding.
- If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.)

Dosage regimen (proper use of this medicine)

- **Your dosage regimen is:**◀◀ :order of your doctor▶▶
- General dosage regimen:
For hypertension, for adults, take 2-4 tablets (5 to 10 mg of the active ingredient) at a time, once daily. The dosage may be adjusted according to the diseases, age or symptoms, however, in patients with renal or renal vascular hypertension, or malignant hypertension, the initial dose may be started at 1 tablet (2.5 mg) at a time. Strictly follow the instructions of your doctor/pharmacist.
For chronic heart failure, for adults, take 2-4 tablets (5 to 10 mg of the active ingredient) at a time, once daily. The dosage may be adjusted according to the age or symptoms, however, in the patients with renal disorder or if you are taking diuretics, the initial dose may be started at 1 tablet (2.5 mg) at a time. Strictly follow the instructions of your doctor/pharmacist.
- Missed dose: 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. DO NOT take double doses to make up for the missed dose.
- Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.
- Others: Do not stop taking the medicine without the instructions of your doctor.

Precautions while using this medicine

- The medicine may cause dizziness or lightheadedness since the blood pressure is decreased. Avoid driving a car, working at heights or operating dangerous machinery after taking the medicine.

Continued on next page.

Side effects of this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: dizziness, cough, etc.

In rare cases, symptoms described below may be the sign of side effects indicated in brackets []. If they occur, stop taking your medicine and check with your doctor immediately.

- breathing difficulty, swelling of the face, tongue or throat [angioedema]
- facial pallor, cold sweat, orthostatic dizziness [shock]
- decreased urine output, general edema, malaise [acute renal failure]
- abdominal pain, nausea [pancreatitis]
- muscular weakness, weakness, numbness in the limbs [hyperkalemia]

Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.

Storage and other information

- Keep the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For doctor use only: Day Month Year

For further information, ask your doctor/pharmacist. Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.