

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

Internal

Revised: 08/2017

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: ENALAPRIL MALEATE TABLETS 5mg 「OHARA」

Active ingredient: Enalapril maleate

Dosage form: light pink tablet, diameter: 6.5 mm, thickness: 2.3 mm

Print on wrapping: エナラプリルマレイン酸塩 5mg「オーハラ」, エナラプリルマレイン酸塩, 5mg, Enalapril Maleate 5mg 「OHARA」



Effects of this medicine

This medicine inhibits angiotensin-conversion enzyme to suppress production of angiotensin II. It subsequently dilates blood vessels and decreases blood pressure to reduce cardiac load.

It is usually used to treat essential hypertension, renal hypertension, renovascular hypertension, malignant hypertension and chronic heart failure (mild to moderate).

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 a history of angioedema.
- If you are on apheresis, hemodialysis or low-salt diet.
- If you have renal artery stenosis, hyperkalemia, renal disorder or cerebrovascular disorder.
- 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 1 to 2 tablets (5 to 10 mg of the active ingredient) at a time, once a day. The dosage may be adjusted according to your age and symptoms. For patient with renal/renovascular hypertension or malignant hypertension, the initial dosage may be started with 0.5 tablet (2.5 mg). In general, for children aged 1 month or over, take 0.08 mg/kg of the active ingredient once a day. The dosage may be adjusted according to your age and symptoms. However, the daily dosage should not exceed 2 tablets (10 mg).
 - **Chronic heart failure (mild to moderate):** This medicine is used in combination with digitalis products or diuretics. In general, for adults, take 1 to 2 tablets (5 to 10 mg of the active ingredient) at a time, once a day. The dosage may be adjusted according to your age and symptoms. For patient with renal disorder or taking diuretics, the initial dosage may be started with 0.5 tablet (2.5 mg).
- This preparation contains 5 mg of the active ingredient anhydride in a tablet. Strictly follow the instructions in any case.
- If you miss a dose, take the missed 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 this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause dizziness or lightheadedness due to decreased blood pressure. Pay attention when performing dangerous operations such as working at heights or driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness and cough. 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.

- swelling of face/tongue/throat with respiratory distress, intestinal angioedema with abdominal pain/nausea/vomiting/diarrhea [angioedema]
- facial pallor, cold sweat, dizziness [shock]
- chest pain, pressurized/constricted feeling in the chest, cold sweat [myocardial infarction, angina pectoris]
- general edema, decreased urine output, headache [acute renal failure]
- high fever more than 38°C, bloodshot eyes, erosion in lips/ocular mucosa [exfoliative dermatitis, toxic epidermal necrosis, mucocutaneous ocular syndrome, pemphigus]

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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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