


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

620004057

Newly-created: 07/2008

<p>Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.</p> <p>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.</p>	
<p>Brand name : Benidipine Hydrochloride tab. 4mg 「 OME 」</p> <p>Active ingredient : Benidipine hydrochloride</p> <p>Dosage form : yellow tablet (: 7.1 mm, thickness: 3.0 mm)</p> <p>Printings on wrapping : (face) ベニジピン塩酸塩 4mg「 OME 」, OH-273, 4mg(back) BENIDIPINE HYDROCHLORIDE 4mg 「 OME 」, ベニジピン塩酸塩 「 OME 」, 4mg</p>	
<p>Effects of this medicine</p> <p>This medicine enlarges the peripheral arteries and the coronary vessels, decreases blood pressure by reducing influx of calcium ion into cells, and consequently prevents or relieves episode of angina. It is usually used for the treatment of hypertension, renal parenchymal hypertension, and angina pectoris.</p>	
<p>Before using this medicine, tell your doctor/pharmacist</p> <ul style="list-style-type: none"> • If you ever experienced any allergic reaction (itch, rash, etc.) to any medicine. <li style="padding-left: 20px;">If you are a patient with cardiogenic shock, hypotension, or hepatic dysfunction. • 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.) 	
<p>Dosage regimen (proper use of this medicine)</p> <ul style="list-style-type: none"> • Your dosage regimen is: _____ :order of your doctor • General dosage regimen: <u>For the treatment of hypertension and renal parenchymal hypertension</u>, for adults, take 1/2 to 1 tablet (2 to 4 mg of the active ingredient) at a time, once daily, after breakfast. If the effect is insufficient, the dosage may be increased up to 2 tablets (8 mg) once daily, however, for patients with severe hypertension, take 1 to 2 tablets (4 to 8 mg) at a time, once daily, after breakfast. <u>For the treatment of angina pectoris</u>, for adults, take 1 tablet (4 mg of the active ingredient) at a time, twice daily, after breakfast and supper. The dosage may be adjusted according to the diseases, age, or symptoms in any case. 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. 	
<p>Precautions while using this medicine</p> <ul style="list-style-type: none"> • The medicine may cause dizziness or lightheadedness due to the antihypertensive action. Pay close attention when you work at heights, drive a car or operate dangerous machinery. • Never take the medicine with a glass of grapefruit juice since the blood pressure may be decreased excessively. 	
<p>Side effects of this medicine</p> <p>Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: palpitation, flash, headache, rash, itch, photosensitivity, gynecomastia, etc.</p> <p>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.</p> <ul style="list-style-type: none"> • general malaise, loss of appetite, yellowness in the skin or white of the eyes [hepatic dysfunction, jaundice] <p>Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.</p>	

Continued on next page.

Storage and other information

- Keep the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- Do not store the remainder and ask your pharmacist how to discard it.

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.

SIE