


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

620904101

Newly-created: 09/2009

<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><b>Brand name : MABLIN POWDER 1%</b></p> <p>Active ingredient : Busulfan</p> <p>Dosage form : white to yellowish white powder</p> <p>Printings on wrapping :</p>	
<p><b>Effects of this medicine</b></p> <p>This medicine inhibits DNA synthesis which is essential for multiplication of cells and consequently suppresses overgrowth of abnormal cells.</p> <p>It is usually used to improve subjective/objective symptoms of chronic myelogenous leukemia or polycythemia vera.</p>	
<p><b>Before using this medicine, tell your doctor/pharmacist</b></p> <ul style="list-style-type: none"> <li>• If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.</li> <li style="padding-left: 20px;">If you are a patient with hepatic/renal disorder, myelosuppression, coexisting infection, lung disorder or chicken pox.</li> <li>• If you are pregnant or breastfeeding.</li> <li>• If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.)</li> </ul>	
<p><b>Dosage regimen (proper use of this medicine)</b></p> <ul style="list-style-type: none"> <li>• <b>Your dosage regimen is:</b> _____ :order of your doctor</li> <li>• General dosage regimen:  <u>For treatment of chronic myelogenous leukemia</u>, (method 1) for adults, take 0.4-0.6 g (4-6 mg of the active ingredient) a day. After monitoring your level of white blood cells decreases to near the baseline (15,000/mm<sup>3</sup>) the dose is decreased to 0.2 g (2 mg) or less a day. (method 2) For adults, take 0.2 g (2 mg of the active ingredient) or less a day till your level of white blood cells decreases to near the baseline (15,000/mm<sup>3</sup>). (both method 1,2) As maintenance therapy, take 0.2 g (2mg) at a time, once in a week or two weeks.  <u>For treatment of polycythemia vera</u>, for adults, 0.2-0.4 g (2-4 mg of the active ingredient) a day. The dose is increased gradually up to 0.6 g (6 mg) a day according to the result of blood tests. After the symptoms are improved, the dose should be decreased and maintained.                      In any case, the dosage should be adjusted to the disease to be treated, age or symptoms. Strictly follow the instructions of your doctor/pharmacist.                 </li> <li>• Missed dose: Take the missed dose as soon as possible. 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.</li> <li>• Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.</li> <li>• Others: Do not stop taking the medicine without the instructions of your doctor.</li> </ul>	
<p><b>Precautions while using this medicine</b></p> <ul style="list-style-type: none"> <li>• While taking the medicine you have laboratory tests (blood test, liver/renal function test) frequently. Do not miss your appointments and have tests orderly.</li> </ul>	
<p><b>Side effects of this medicine</b></p> <p>Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: rash, urticaria, etc.</p> <p><b>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.</b></p> <ul style="list-style-type: none"> <li>• anemia, fever, bleeding tendency [ myelosuppression ]</li> <li>• fever, cough, breathing difficulty [ interstitial pneumonia, pulmonary fibrosis ]</li> <li>• sensitive to bright light, foggy vision, failing eyesight [ cataract ]</li> </ul> <p><b>Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.</b></p>	

Continued on next page.

**Storage and other information**

- Keep out the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacy how to discard.

**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.

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