


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

620009127

Newly-created: 03/2009

<p>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.</p>	
<p>Brand name : NU-LOTAN Tablets 50mg Active ingredient : Losartan potassium Dosage form : white tablet (φ : 7.6 mm, thickness: 3.3mm) Printings on wrapping : ニューロタン 50mg</p>	
<p>Effects of this medicine This medicine decreases blood pressure with angiotensin II-receptor antagonistic activity. It also reduces the deterioration of the renal function by reducing proteinuria to protect the kidneys. It is usually used in the treatment of hypertension, and diabetic nephropathy in the type 2 diabetes mellitus accompanied by hypertension and proteinuria.</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. If you have a history of hepatic or renal disorder, or cerebrovascular disorder (cerebral stroke etc.). • 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: For hypertension, for adults, take a half to 1 tablet (25 to 50 mg of the active ingredient) at a time, once daily. The dosage may be adjusted according to the age or symptoms, or may be increased up to 2 tablets (100 mg) daily. Strictly follow the instructions of your doctor/pharmacist. For diabetic nephropathy*, for adults, take 1 tablet (50 mg of the active ingredient) at a time, once daily. The dosage may be increased up to 2 tablets (100 mg) daily according to the blood pressure level. If you have the potential to develop excessive hypotension, the initial dose is started at a half tablet (25 mg). 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. • *: diabetic nephropathy in the type 2 diabetes mellitus accompanied by hypertension and proteinuria. 	
<p>Precautions while using this medicine</p> <ul style="list-style-type: none"> • The medicine may cause dizziness or lightheadedness since the blood pressure is decreased. Avoid working at heights, driving a car or operating dangerous machinery. 	
<p>Side effects of this medicine Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: headache, dizziness, vomiting, nausea, hot flush, hyperkalemia, hypotension, asthenia, fatigue, 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.</p> <ul style="list-style-type: none"> • urticaria, breathing difficulty, edema [anaphylactoid symptoms] • swelling of the face, lips, tongue, or throat [angioedema] • decreased urine output, generalized edema [renal failure] • cold sweat, nausea, loss of consciousness [shock, faint, unconsciousness] <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.
- 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.