

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

610451020

Revised: 11/2011

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 : Fosamac Tablets 5**

Active ingredient : Alendronate sodium hydrate

Dosage form : white tablet (φ : 8.0 mm, thickness: 3.2 mm)

Printings on wrapping : フォサマック 5, 万 925



**Effects of this medicine**

This medicine is taken up by bone surfaces, which have osteoclasts, to reduce bone resorption and increase bone mass by suppressing the osteoclast activities, and consequently make bones resistant to fractures.

It is usually used in the treatment of osteoporosis.

**Before using this medicine, tell your doctor/pharmacist**

- If you ever experienced any allergic reaction (itch, rash, etc.) to any medicine.  
If you are a patient with esophageal stricture, or esophageal disorder such as swallowing difficulty.  
If you are unable to stand or sit upright for at least 30 minutes.  
If you are a patient with hypocalcemia.  
If you are receiving dental treatment such as tooth extraction or implant.
- 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 adults, take 1 tablet (5 mg of the active ingredient) at a time, with 180 mL of water, once daily, first thing in the morning. However, you should not lie down, eat and drink (except water), and avoid taking other medicine for at least 30 minutes after taking the medicine. Strictly follow the instructions of your doctor/pharmacist.
- Never take the medicine with mineral water of high calcium and magnesium content (higher than hardness 300).
- Missed dose: Skip the missed dose and continue your regular dosing schedule on the next morning. 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**

- Try to ingest calcium through food.
- Keep the mouth clean.

**Side effects of this medicine**

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: nausea, constipation, diarrhea, gastritis, gastric pain, 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.**

- heartburn, odynophagia, hematemesis [esophageal disorder, intraoral disorder]
- hematemesis, bloody stool, epigastric pain [gastric disorder, duodenal disorder]
- erythema, blister, fever [Stevens-Johnson syndrome, toxic epidermal necrolysis]
- pain in jaw, loose teeth, swelling of the gum [jaw bone necrosis, jaw osteomyelitis]
- The pain of the thigh or an inguinal region [atypical subtrochanteric and diaphyseal femoral fractures]

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

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. "Kanjamuke Iyaku Hin Guide" and Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.