

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

Internal  
Revised: 02/2014

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:** Alendronate Tablets 35mg "Nichiiko"

**Active ingredient:** Alendronate sodium hydrate

**Dosage form:** white tablet, major axis 10.3mm, minor axis 5.6mm, thickness 3.6mm

**Print on wrapping:** アレンドロン酸錠 35mg「日医工」, 週 1 回 1 錠のむお薬です(毎日のむお薬ではありません), のみ方, のんだ後



## **Effects of this medicine**

This medicine suppresses bone resorption by acting upon cells (osteoclasts) which destroy bone tissue, thereby increasing bone mass and making bones resistant to fractures.

It is usually used to treat osteoporosis.

## **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 esophageal stricture or any disorder delaying the passage of esophagus.  
If you are unable to stand or sit upright for more than 30 minutes.  
If you have hypocalcemia.
- If you are 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 >>
- In general, for adults, take 1 tablet (35 mg of alendronate) at a time, once a week on awaking, with adequate amount of water (about 180 mL). Avoid lying down, drinking any beverages (including mineral water with particularly high content of calcium, magnesium, etc.) other than water and taking any foods and other medicines for at least 30 minutes after taking the medicine. Strictly follow the instructions.
- This medicine may irritate your mouth and throat. Avoid chewing or sucking this medicine. Do not take this medicine before going to bed or while lying in bed.
- By the time you have realized you missed a dose, but have not taken any foods or beverages, take the missed dose as soon as possible. If you have taken some foods or beverages, skip the missed dose for the day and take a dose at the time of awaking the next day. Thereafter, return to your designated dosing date and 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**

- Try to ingest calcium through meals, etc.
- Maintain your oral hygiene while taking this medicine.
- Inform your dentist or oral surgeon that you are taking this medicine when you receive the dental treatment such as extraction.

## **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include stomach/epigastric pain, stomach discomfort, abdominal discomfort, nausea, dyspepsia and diarrhea. 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.**

- hematemesis, melena, aphagia [esophageal/intraoral disorder]
- hematemesis, melena, upper abdominal pain [gastric/duodenal disorder]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [liver dysfunction, jaundice]
- convulsion, numbness, disorientation [hypocalcemia]
- high fever, bloodshot eyes, erythema [toxic epidermal necrolysis, mucocutaneous-ocular syndrome]

**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. Ask the pharmacist or medical facility how to discard unneeded medicine.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.