

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

Internal

Revised: 01/2023

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: Bonoteo Tablets 50mg

Active ingredient: Minodronic acid hydrate

Dosage form: very light red tablet, major axis: approx. 13.1 mm, minor axis: approx. 7.0 mm, thickness: approx. 4.1 mm

Imprint or print on wrapping: ボノテオ 50mg, Bonoteo, 4週に1回1錠, 骨粗鬆症治療剤



Effects of this medicine

This medicine inhibits osteoclastic bone resorption and increases bone density and bone strength, thus preventing bone fracture.

It is usually used for the treatment of osteoporosis.

The following patients may need to be careful when 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 or foods.
- If you have a disorder that delays esophageal transit such as esophageal stenosis or achalasia.
- If you are unable to sit upright for more than 30 minutes when taking this medicine.
- If you have: hypocalcemia, dysphagia (difficulty in swallowing), upper gastrointestinal disorders such as esophagitis, gastritis, duodenitis and ulcer or renal disorder.
- If you are pregnant, possibly 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 (50 mg of the active ingredient) at a time, once every 4 weeks, with a cup (approximately 180 mL) of water (or lukewarm water), before the first meal or beverage of the day. At least for the first 30 minutes after taking the medicine, do not lie down, and refrain from eating, drinking (including mineral water that contains plenty of minerals such as calcium and magnesium) or taking other medicine, except water. Strictly follow the instructions.
- This medicine may irritate the inside of the mouth and throat. Do not crunch or dissolve the medicine in the mouth.
- Do not take this medicine at bedtime or before rising.
- Consult with your doctor, and receive dental checkup prior to taking this medicine as needed. If possible, have your dental treatment, such as tooth extraction, and complete it by the time you start this medicine.
- If you miss a dose, take the missed dose in the morning on the following day, and follow your regular dosing schedule from the next dose onwards (You should not take two doses on one day). If you missed a regular dose, consult your doctor/pharmacist at the next visit and report that you missed a dose and took the missed dose on another day.
- 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

- This medicine may cause upper gastrointestinal disorders such as duodenal or gastric ulcers. If any symptoms such as heartburn, nausea, vomiting, blood in vomit (fresh red to brownish- or blackish-brown), abdominal pain or black stool appear, stop using this medicine and visit your doctor immediately.
- Osteonecrosis of the jaw and osteomyelitis of the jaw may occur in the patients who are using bisphosphonates including this medicine. Since such adverse reactions have reported to be associated with dental treatments such as tooth extraction, receive adequate explanations about the following points from your doctor or pharmacist:
 - Maintain your oral hygiene by brushing your teeth.
 - Undergo an oral or dental checkup regularly.
 - Inform your dentist that you are taking this medicine when you receive dental treatment.
 - Avoid any treatments such as tooth extraction as much as possible while taking this medicine.
 - If abnormalities in the teeth/jaw (such as jaw pain, looseness of the teeth or swelling of the gum) occur, visit a dentist or oral surgeon immediately.
- The onset of osteonecrosis of the external auditory canal has been reported in patients who are using bisphosphonates. According to some of these cases, osteonecrosis has developed in association with ear infection or wound. If symptoms of otitis externa such as itch or pain in the ear, hotness inside the ear, otorrhea (ear

discharge) or abnormal feeling in the ear persist, visit an otolaryngologist.

- Fractures at the groin have been reported in patients who are using bisphosphonates for a long period. Before these fractures occur, there would be signs such as pain of the thigh or groin. If any of these symptoms occur, visit your doctor immediately.
- Try to consume calcium and vitamin D from food, etc. However, since intake of calcium supplement or medicines containing calcium, aluminium or magnesium may prevent the absorption of this medicine, these products should be taken at least 30 minutes apart after taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include stomach/abdominal discomfort, abdominal pain and gastritis. 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.

- epigastric pain, tenderness, vomiting [upper gastrointestinal disorder]
- tooth/gum/jaw pain, swelling and pus discharge of the gum, looseness of the teeth [osteonecrosis of the jaw/osteomyelitis of the jaw]
- otitis externa (itch in the ear, hotness inside the ear, abnormal feeling in the ear), ear discharge, ear pain [osteonecrosis of external auditory canal]
- pain in the thighs or groin, pain in the forearm (wrist to around elbow) [atypical fracture of femoral subtrochanteric section/shaft of proximal femoral/proximal ulna]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]

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 reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.