

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

Internal

Revised: 06/2020

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: approximately 13.1 mm, minor axis: approximately 7.0 mm, thickness: approximately 4.1 mm

Print on wrapping: (Face) ボノテオ 50mg, Bonoteo, (Back) 4週に1回1錠, ボノテオ 50mg, 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.

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 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.
- 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 calcium or 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.
- 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

- Maintain your oral hygiene while taking this medicine. Otherwise pain or swelling of the jaw, numbness of the jaw and loosening of the teeth may occur.
- If you receive dental treatment, report to your dentist or oral surgeon that you are taking this medicine.
- Try to consume calcium and vitamin D from food, etc. However, since intake of food, beverages or vitamin supplements that contain a considerable amount of calcium may affect 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/gingival/jaw pain, swelling and pus discharge of the gingiva, looseness of the teeth [osteonecrosis of the jaw, osteomyelitis of the jaw]
- otitis externa (itch of the ear, hotness in the ear, discomfort of the ear), ear discharge, ear pain [osteonecrosis of external auditory canal]
- pain in the thighs or inner groin [atypical femoral subtrochanteric fracture and atypical femoral hip and shaft fractures]
- 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 away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to discard.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.