

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: BENET Tablets 75mg

Active ingredient: Sodium risedronate hydrate

Dosage form: light yellow oval tablets, major diameter: 10.2 mm, minor diameter: 5.2 mm, thickness: approx. 4.2 mm

Imprint or print on wrapping: (Face) ベネット錠 75mg 312

(Back) ベネット錠 75mg 312 BENET Tablets 75mg



Effects of this medicine

This medicine suppresses bone resorption by acting upon cells which destroy bone tissue (osteoclasts), thereby producing an increase in bone mass and making bones less predisposed to fractures.

It is usually used to treat 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 esophageal obstruction, gastric ulcer, duodenal ulcer, esophagitis, hypocalcemia or renal disorder.
If you are unable to remain in standing or sitting position for 30 minutes or longer after taking this medicine.
- 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 (75 mg of sodium risedronate) at a time, once a month on awakening, with an adequate amount (about 180 mL) of water or lukewarm water without chewing or licking. Do not lie down for 30 minutes after taking this medicine. Do not ingest beverages or foods except water, nor any other medicines, during the 30-minute period after taking this medicine. Strictly follow the instructions.
- Do not take this medicine together with beverages except water (including mineral water which is rich in calcium and magnesium, etc., milk, coffee or juice), foods, nor any other medicines.
- Take this medicine on the same day of the month.
- If you miss a dose, take the missed dose as soon as possible unless you have ingested any beverage or food by that time of the day. If you have ingested any beverage or food already, then do not take the missed dose on that day, and take that missed dose the following morning. Take the next dose on the pre-appointed day of a month. 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

- Take adequate calcium from meals, etc.
- Necrosis of the jaw bone or osteomyelitis of the jaw may occur in patients receiving treatment with bisphosphonates. Receive a full explanation about the followings from your doctor or pharmacist since many adverse reactions of this medicine occur associated with dental treatments such as tooth extraction.
 - Consult with your doctor and receive dental checkups before starting this medicine as necessary, and try to complete treatment such as tooth extraction as much as possible.
 - Keep your oral cavity clean by brushing, etc. while taking this medicine.
 - Receive regular dental checkups while taking this medicine.
 - When you visit a dentist while taking this medicine, be sure to tell the dentist that you are taking it.
 - Try to avoid dental treatments such as tooth extraction as much as possible while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, stomach discomfort, gastritis, upper abdominal pain, headache, joint pain, back pain, bone pain, muscle pain, neck pain and fever. 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.

- chest/abdominal pain, difficulty in swallowing, heart burn, nausea/vomiting, black stool [upper gastrointestinal

disorders (esophageal perforation, esophageal constriction, esophageal ulcer, gastric ulcer, esophagitis, duodenal ulcer, etc.)]

- yellowing of the skin or white of the eyes, dullness, loss of appetite [liver dysfunction, jaundice]
- pain and swelling of the chin, numbness of the chin, loosened teeth [necrosis of the jaw bone, osteomyelitis of the jaw]
- itch/heat sensations/strange sensations in the ear, otorrhea, ear pain [osteonecrosis of the external auditory canal]
- pain in the thigh, inguinal region or forearm [atypical subtrochanteric, proximal diaphyseal femoral and proximal ulnar diaphyseal fractures]

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. If you do not know how to dispose of the unused medicines, seek advice of your 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.