BONDRIX

IBANDRONIC ACID INN

Compositions:
Bondrix Tablet: Each film-coated tablet contains Ibandronate monosodium monohydrate INN equivalent to 150 mg Ibandronic Acid.

Pharmacology:
Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common in women after menopause. It also affects men. At first, osteoporosis has no symptoms, but people with osteoporosis may develop loss of height and are more likely to break (fracture) their bones, especially the back (spine), wrist, and hip bones. Osteoporosis can be prevented and with proper therapy it can be treated. Ibandronic acid inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to a progressive gain in bone mass. The absorption of ibandronate occurs in the upper gastrointestinal tract. After absorption, ibandronate either rapidly binds to bone or is excreted unchanged into urine.

Dosage And Administration:
Dose: The recommended dose of Bondrix for the treatment and prevention of osteoporosis is one 150 mg tablet once-a-month. Special dosage instructions: Patients with Hepatic Impairment: No dose adjustment is necessary. Patients with Renal Impairment: No dose adjustment is necessary for patients with mild or moderate renal impairment where creatinine clearance is equal to or greater than 30 mL/min. Geriatric Patients: No dose adjustment is necessary in the elderly. Administration: • The tablet should preferably be taken on the same date of each month. • To maximize absorption and clinical benefit, Bondrix should be taken at least 60 minutes before the first food or drink or any oral medication or supplementation (including calcium). • To facilitate delivery to the stomach and reduce the potential for esophageal irritation, Bondrix should be swallowed whole with a full glass of plain water. • The tablet should not be chewed or sucked. • Patients should not lie down for 60 minutes after taking Bondrix. However, patients can sit down, walk, exercise or do the regular activities. • If the once-monthly dose is missed and the patient's next scheduled Bondrix day is more than 7 days away, the patient should be instructed to take one Bondrix 150 mg tablet in the morning following the date that it is remembered. Then the patient should return to the original schedule. • If the next scheduled dose is within 7 days, patients should wait until the next dose and then continue taking one tablet once-a-month as originally scheduled. Two 150 mg tablets should not be taken within the same week.

Contraindications:
Bondrix is contraindicated in patients with - • Known hypersensitivity to Ibandronic acid or to any of its excipients • Uncorrected hypocalcemia • Inability to stand or sit upright for at least 60 minutes.

Warning And Precaution:
Precautions: • Adequate intake of calcium and vitamin D is important in all patients. • Patients should also pay particular attention to and be able to comply with the dosing instructions to minimize the risk of gastrointestinal side effects. Bondrix may cause upper gastrointestinal disorders such as dysphagia, esophagitis. So patient should comply with the dosing instructions.

Side Effects:
The main side effects of ibandronic acid are dyspepsia, nausea, diarrhea, abdominal pain,

muscle aches, headaches, dizziness.

Use in Pregnancy and Lactation:
Pregnancy Category C. Bondrix should not be used during pregnancy and lactation.

Drug Interaction:
It is likely that products containing calcium and other multivalent cations (such as aluminium, magnesium, iron) including milk, food, and antacids are likely to interfere with absorption of Ibandronate. Therefore, patients must wait 60 minutes after taking Bondrix before taking other oral medications.

Overdosage:
No specific information is available on the treatment of overdose with Ibandronic acid. However, oral overdose may result in hypocalcemia, hypophosphatemia, upset stomach, dyspepsia, esophagitis, gastritis. Milk or antacids should be given to bind Bondrix.

Storage:
Store in a cool and dry place below 30° C. Protect from light and moisture.

Packing:
Bondrix Tablet: Each box contains 1 film coated tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.