Ibandron®

Ibandronic Acid INN 150 mg

Film Coated Tablet

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

Planning to choose Ibandron® Day:
The dose of **Ibandron®** is one tablet once a month
Choose one day of the month that will be easy to remember:

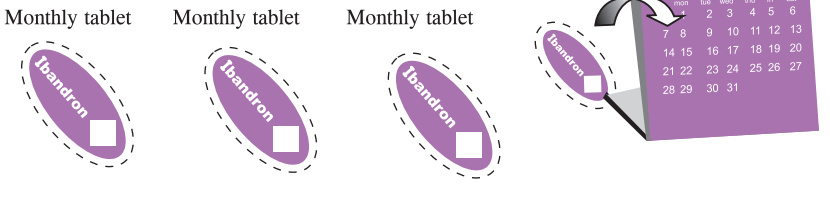
- Either the same date (such as 1st date of each month)
- Or the same day (such as the first Sunday of each month)

Use the peel-off stickers (provided on next page) to mark the dates on your calendar.

Put a tick in the box on the sticker after taking **Ibandron®**.

Contact your doctor when you need.

Peel-off stickers for your calendar
আপনার ক্যালেন্ডারের জন্য পিল-অফ ষ্টিকার



It is important to keep taking **Ibandron®** every month on the same date
প্রতি মাসের একই তারিখে ইবানড্রন® সেবন করা গুরুত্বপূর্ণ

Composition:
Ibandron® Tablet: Each film coated tablet contains Ibandronate Sodium INN equivalent to Ibandronic Acid 150 mg.

Pharmacology:
The action of Ibandronic Acid on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone. Ibandronic Acid inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass.

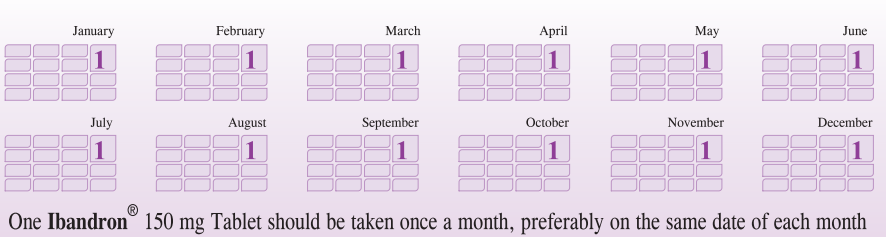
Indications:
Ibandron® is indicated for the treatment and prevention of osteoporosis in postmenopausal women. **Ibandron®** increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

Dosage and administration:
The dose of **Ibandron®** is one 150 mg tablet once monthly on the same date of each month.

Instructions for patient

The following points should be ensured when taking Ibandron®:

1. One **Ibandron®** 150 mg Tablet should be taken once a month, preferably on the same date of each month.
2. In case, a monthly dose is missed, patient can take the tablet within next 21 days. Patient should then return to take their dose once a month on the actually scheduled date.
3. After rising in the morning, patient should take **Ibandron®** in an empty stomach with a full glass of plain water while sitting or standing in an upright position.
4. Fruit juice, milk or any other liquid except water cannot be taken with **Ibandron®**.
5. After taking **Ibandron®**, patient can usually sit or walk around but must not lie down or take any food or liquid for 1 hour.



One **Ibandron®** 150 mg Tablet should be taken once a month, preferably on the same date of each month

After rising in the morning, patient should take **Ibandron®** in an empty stomach with a full glass of plain water while sitting or standing in an upright position

After taking **Ibandron®**, patient can usually sit or walk around for 1 hour

Fruit juice, milk or any other liquid except water cannot be taken with **Ibandron®**

After taking **Ibandron®**, patient must not take any food or liquid for 1 hour

After taking **Ibandron®**, patient must not bend or lie down in bed for 1 hour

If the once-monthly dose is missed, and the patient's next scheduled **Ibandron®** day is more than 7 days away, the patient should be instructed to take one **Ibandron®** 150 mg tablet in the morning following the date that it is remembered. The patient should then return to taking one **Ibandron®** 150 mg tablet every month in the morning of their chosen day, according to their original schedule.

The patient must not take two 150 mg tablets within the same week. If the patient's next scheduled **Ibandron®** day is only 1 to 7 days away, the patient must wait until their next scheduled **Ibandron®** day to take their tablet. The patient should then return to taking one **Ibandron®** 150 mg tablet every month in the morning of their chosen day, according to their original schedule.

Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate. Intake of supplemental calcium and vitamin D should be delayed for at least 1 hour following oral administration of **Ibandron®** in order to maximize absorption of **Ibandron®**.

Physicians should be alert to signs or symptoms signaling a possible esophageal reaction during therapy, and patients should be instructed to discontinue **Ibandron®** and seek medical attention if they develop symptoms of esophageal irritation such as new or worsening dysphagia, pain on swallowing, retrosternal pain, or heartburn.

Contraindications:
Ibandronic Acid is contraindicated in any patient who has shown a hypersensitivity reaction to the drug or to any of the excipients, hypocalcemia and inability to stand or sit upright for at least 1 hour.

Side effects:
The most common side effects include back pain, allergic reaction, dyspepsia, diarrhea, nausea, vomiting, gastritis, myalgia, headache, dizziness, vertigo etc.

Precautions:
Hypocalcemia and other disturbances of bone and mineral metabolism should be effectively treated before starting therapy with Ibandronic Acid. Adequate intake of calcium and vitamin D is important in all patients. It is not recommended for use in patients with severe renal impairment (creatinine clearance <30 mL/min).

Use in special groups:
Use in pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

Use in nursing mothers: It is not known whether it is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when it is administered to a nursing woman.

Pediatric use: Safety and effectiveness in pediatric patients have not been established.

Geriatric use: No overall differences in effectiveness or safety were observed between elderly patients and younger patients. Therefore, no dosage adjustment is necessary in the elderly.

Hepatic Insufficiency: No studies have been performed to assess the pharmacokinetics of Ibandronic Acid in patients with hepatic impairment because Ibandronic Acid is not metabolized in the human liver.

Renal Insufficiency: It is not recommended for use in patients with severe renal impairment (creatinine clearance of $<$ 30 mL/min).

Drug interactions:
Products containing calcium and other multivalent cations (such as aluminum, magnesium, iron), including milk, food, and antacids are likely to interfere with absorption of Ibandronic Acid.

It should be taken at least 1 hour before any oral medications, including medications containing multivalent cations (such as antacids, supplements or vitamins). Also, patients should wait at least 1 hour after dosing before taking any other oral medications. Caution should also be exercised in the concomitant use of aspirin or NSAIDs with Ibandronic Acid.

Storage:

- Store below 30^0C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:
Ibandron®Tablet: Each box contains 1 tablet in alu-alu blister pack.

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