Once-Monthly
Ibnate®
(Ibandronic Acid)
Tablets
150mg

آئبنیٹ ۱۵۰ ملی گرام
(آئی بینڈرونک ایسڈ) ٹیبلٹس

How to use IBNATE : 1.Choose the date/day of the month that will be easy to remember: - Either the same date (for example the 1st or 5th or any other date of each month) - Or the same day (for example the first Sunday or Friday or any other day of each Month). **2.** When you get out of the bed on the day you have chosen, before taking your first Food, beverage or other medication, take on Ibnate Once Monthly 150mg tablet with a full glass of plain water. **3.** Continue your morning activities: You can sit stand or walk-just stay fully upright, Don't lie down, eat, drink or take Other medication for at least 1 hour. After that you are free for all. **4.** Remember; take Ibnate Once Monthly 150mg tablet each month on same date/day if you miss the dose, just take one Ibnate tablet on the morning after you remember, unless the time to the next scheduled dose is within 7 days. You should then return to taking your dose once a month on your originally scheduled date.

DESCRIPTION: IBNATE (Ibandronic Acid) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The chemical name for Ibandronic is 3-(N-methyl-N-pentyl) amino-1-hydroxy-propane-1,1diphosphonic acid, monosodium salt, monohydrate with the molecular formula $C_9H_{22}NO_7P_2Na.H_2O$ and a molecular weight of 359.24. Ibandronic has the following structural formula:

COMPOSITION: Each film-coated tablet contains: Ibandronate Sodium Monohydrate eq. to Ibandronic Acid.....150mg, Genix Specs.

CLINICAL PHARMACOLOGY: Mechanism of Action: The action of Ibandronate on bone tissue is based on its affinity for hydroxyapatite, part of the mineral matrix of bone. Ibandronate 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. **Pharmacodynamics:** IBNATE (Ibandronic Acid) produced biochemical changes indicative of dose-dependent inhibition of bone resorption, including decreases of biochemical markers of bone collagen degradation (such as deoxypyridinoline, and cross-linked C-telopeptide of Type I collagen) in once-monthly doses from 100 mg to 150 mg in postmenopausal women. **Pharmacokinetics: Absorption:** The absorption of oral ibandronic Acid occurs in the upper gastrointestinal tract. Plasma concentrations increase in a dose-linear manner up to 50 mg oral intake and increases nonlinearly above this dose. Following oral dosing, the time to maximum observed plasma Ibandronate concentrations ranged from 0.5 to 2 hours (median 1 hour) in fasted healthy postmenopausal women. The mean oral bioavailability of 2.5 mg ibandronate was about 0.6% compared to intravenous dosing. The extent of absorption is impaired by food or beverages (other than plain water). The oral bioavailability of ibandronate is reduced by about 90% when administered concomitantly with a standard breakfast in comparison with bioavailability observed in fasted subjects. Bioavailability and the effect on bone mineral density (BMD) are reduced when food or beverages are taken less than 60 minutes following an ibandronate dose.

Distribution: After absorption, Ibandronic Acid either rapidly binds to bone or is excreted into urine. In humans, the apparent terminal volume of distribution is at least 90 L, and the amount of dose removed from the circulation via the bone is estimated to be 40% to 50% of the circulating dose.

INDICATIONS AND USAGE: IBNATE (Ibandronic Acid) is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

DOSAGE AND ADMINISTRATION: The dose of IBNATE (Ibandronic Acid) is one 150 mg tablet taken once monthly on the same date each month. **Use in Specific Populations:** No dose adjustment is necessary for patients with mild or moderate renal impairment. No dose adjustment is necessary for the elderly, or for patients with hepatic impairment.

CONTRAINDICATIONS: Known hypersensitivity to IBNATE (Ibandronic Acid) or to any of its excipients, Hypocalcemia, Inability to stand or sit upright for at least 60 minutes

WARNINGS AND PRECAUTIONS: Upper Gastrointestinal Adverse Reactions: IBNATE, (Ibandronic Acid) like other bisphosphonates administered orally, may cause upper gastrointestinal disorders such as dysphagia, esophagitis, and esophageal or gastric ulcer. Advise patients to comply with the dosing instructions to minimize the risk of these effects. Discontinue use if new or worsening symptoms develop. **Hypocalcemia and Mineral Metabolism:** Treat hypocalcemia and other disturbances of bone and mineral metabolism before starting IBNATE therapy. Adequate intake of calcium and vitamin D is important in all patients to prevent hypocalcemia. **Musculoskeletal Pain:** Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking IBNATE and other bisphosphonates. The time to onset of symptoms varied from one day to several months after starting the drug. Most patients had relief of symptoms after stopping. A subset had recurrence of symptoms when rechallenged with the same drug or another bisphosphonate. Consider discontinuing use if severe symptoms develop.

Jaw Osteonecrosis: Osteonecrosis, primarily in the jaw, has been reported in patients treated with bisphosphonates. Most cases have been in cancer patients undergoing dental procedures, but some have occurred in patients with postmenopausal osteoporosis or other diagnoses. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), and co-morbid disorders (e.g., anemia, coagulopathy, infection, pre-existing dental disease). Most reported cases have been in patients treated with bisphosphonates intravenously but some have been in patients treated orally. For patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment. **Severe Renal Impairment:** IBNATE is not recommended for use in patients with severe renal impairment (creatinine clearance of <30 mL/min).

ADVERSE REACTIONS: Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates

observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Treatment and Prevention of Postmenopausal Osteoporosis Adverse Events (Draw Table)

BODY SYSTEM/ADVERSE EVENT	Ibandronic Acid 150 mg Monthly % (n=396)
Vascular Disorders	
Hnoisnetrepy	6.3
Gastrointestinal Disorders	
Dyspepsia	5.6
Nausea	5.1
Diarrhea	5.1
Constipation	4.0
Abdominal Pain	7.8
Musculoskeletal and Connective Tissue Disorders	
Arthralgia	5.6
Back Pain	4.5
Pain in Extremity	1.3	4.0
Localized Osteoarthritis	1.3	3.0
Myalgia	0.8	2.0
Muscle Cramp	2.0	1.8
Nervous System Disorders		
Headache	4.1	3.3
Dizziness	1.0	2.3
General Disorders and Administration Site Conditions		
Influenza-like Illness	0.8	3.3
Skin and Subcutaneous Tissue Disorders		
Rash	1.3	2.3
Psychiatric Disorders		
Insomnia	0.8	2.0

Gastrointestinal Adverse Events: The incidence of adverse events in the Ibandronic Acid 150 mg monthly groups were: dyspepsia (6%), diarrhea (5%), and abdominal pain (8%).

Musculoskeletal Adverse Events: The incidence of adverse events in the Ibandronic Acid 150 mg monthly groups were: back pain (5%), arthralgia (6%) and myalgia (2%).

Acute Phase Reactions: Symptoms consistent with acute phase reactions have been reported with bisphosphonate use. Over the two years of the study, the overall incidence of acute phase reaction symptoms was 9% in the Ibandronic Acid 150 mg monthly group. These incidence rates are based on the reporting of any of 33 acute-phase reaction like symptoms within 3 days of the monthly dosing and lasting 7 days or less. Influenza like illness was reported in 2% in the Ibandronic Acid 150 mg monthly group. **Ocular Adverse Events:** Two patients who received Ibandronic Acid 150 mg once-monthly experienced ocular inflammation, one was a case of uveitis and the other scleritis. One hundred sixty (160) postmenopausal women without osteoporosis participated in a 1-year, double-blind, placebo-controlled study of Ibandronic Acid 150 mg once-monthly for prevention of bone loss. Seventy-seven subjects received Ibandronic Acid and 83 subjects received placebo. The overall pattern of adverse events was similar to that previously observed. **Hypersensitivity:** Allergic reactions including anaphylaxis, angioedema, bronchospasm and rash have been reported. **Hypocalcemia:** pocalcemia has been reported in patients treated with Ibandronic Acid. **Musculoskeletal Pain:** Bone, joint, or muscle pain (musculoskeletal pain), described as severe or incapacitating, has been reported. **Jaw Osteonecrosis:** Osteonecrosis of the jaw has been reported in patients treated with Ibandronic Acid.

DRUG INTERACTIONS: Calcium Supplements/Antacids: Products containing calcium and other multivalent cations (such as aluminum, magnesium, iron) are likely to interfere with absorption of IBNATE. IBNATE should be taken at least 60 minutes before any oral medications, including medications containing multivalent cations (such as antacids, supplements or vitamins). Also, patients should wait at least 60 minutes after dosing before taking any other oral medications. **Aspirin/Nonsteroidal Anti-Inflammatory Drugs (NSAIDs):** Because aspirin, NSAIDs, and bisphosphonates are all associated with gastrointestinal irritation, caution should be exercised in the concomitant use of aspirin or NSAIDs with IBNATE.

8 USE IN SPECIFIC POPULATIONS: Pregnancy: Category C: There are no adequate and well-controlled studies in pregnant women. IBNATE should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. **Nursing Mothers:** It is not known whether IBNATE is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when IBNATE 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 these patients and younger patients but greater sensitivity in some older individuals cannot be ruled out.

OVERDOSAGE: No specific information is available on the treatment of overdosage of IBNATE. However, based on knowledge of this class of compounds, oral overdosage may result in hypocalcemia, hypophosphatemia, and upper gastrointestinal adverse events, such as upset stomach, dyspepsia, esophagitis, gastritis, or ulcer. Milk or antacids should be given to bind IBNATE. Due to the risk of esophageal irritation, vomiting should not be induced, and the patient should remain fully upright. Dialysis would not be beneficial.

INSTRUCTIONS: Dosage once monthly or as directed by the physician. Store below 30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children.

PRESENTATION: IBNATE (Ibandronic Acid) tablet is available in Alu-Alu blister Pack of 1's.

ہدایات:

خوراک ایک ٹیبلٹ مہینے میں ایک دفعہ یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی، گرمی اور نمی سے محفوظ رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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