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Osfit Tablet* 150 mg

COMPOSITION: *Each tablet contains:*
Ibandronate Sodium Monohydrate eq. to Ibandronic acid* 150 mg

DESCRIPTION: Ibandronate sodium monohydrate is a nitrogen-containing bisphosphonate. The chemical name for ibandronate sodium is 3-(N-methyl-N-pentyl) amino-1-hydroxypropane-1,1diphosphonic acid, monosodium salt, monohydrate with the molecular formula $C_9H_{22}NO_7P_2Na \cdot H_2O$ and a molecular weight of 359.24.

PHARMACOLOGY: *Pharmacodynamics:* Ibandronic acid is a highly potent bisphosphonate belonging to the nitrogen-containing group of bisphosphonates, which act on bone tissue and specifically inhibit osteoclastic activity reducing bone resorption and turnover. It does not interfere with osteoclast recruitment. The action of ibandronic acid on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to, on average, a net gain in bone mass. Daily or intermittent administration of ibandronic acid results in reduced bone resorption as reflected in reduced levels of serum and urinary biochemical markers of bone turnover, increased BMD and a decreased incidence of fractures. *Pharmacokinetics:* The absorption of ibandronic acid in the upper gastrointestinal tract is rapid after oral administration and plasma concentrations increase in a dose-proportional manner up to 50 mg oral intake, with greater than dose-proportional increases seen above this dose. Maximum observed plasma concentrations were reached within 0.5 to 2 hours (median 1 hour) in the fasted state and absolute bioavailability was about 0.6%. The extent of absorption is impaired when taken together with food or beverages (other than plain water). Bioavailability is reduced by about 90% when ibandronic acid is administered with a standard breakfast in comparison with bioavailability seen in fasted subjects. There is no meaningful reduction in bioavailability provided ibandronic acid is taken 60 minutes before a meal. After initial systemic exposure, ibandronic acid 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 reaching the bone is estimated to be 40-50% of the circulating dose. Protein binding in human plasma is low (approximately 85% bound at therapeutic concentrations), and thus there is a low potential for drug-drug interaction due to displacement. The absorbed fraction of ibandronic acid is removed from the circulation via bone absorption (40-50%) and the remainder is eliminated unchanged by the kidneys. The unabsorbed fraction of ibandronic acid is eliminated unchanged in the feces. Terminal half-life is generally in the range of 10-72 hours.

INDICATIONS: Osfit Tablet 150 mg is indicated for the treatment of postmenopausal osteoporosis, to reduce the risk of fractures.Ê*Treatment of Osteoporosis:*ÊOsteoporosis may be confirmed by the finding of total bone density (T-score <-2.5) and the presence or history of osteoporotic fracture, or total bone density (T-score <-2.5) in the absence of documented pre-existing osteoporotic fracture.Ê

CONTRAINDICATIONS:

- Ibandronic acid is contraindicated in patients with known hypersensitivity to ibandronic acid or to any of the excipients.
- Ibandronic acid is contraindicated in patients with uncorrected hypocalcemia. As with all bisphosphonates indicated in the treatment of osteoporosis, pre-existing hypocalcemia needs to be corrected before initiating therapy with Ibandronic acid.
- Ibandronic acid is contraindicated in renal failure.
- Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia.
- Inability to stand or sit upright for at least 60 minutes.

POSSIBLE ADVERSE EFFECTS: The common side effects seen with Ibandronic acid are headache, oesophagitis, gastritis, gastro-oesophageal reflux disease, dyspepsia, diarrhoea, abdominal pain, nausea, rash, arthralgia, myalgia, musculoskeletal pain, muscle cramp, musculoskeletal stiffness & influenza like illness. Transient, influenza-like, symptoms have been reported with Ibandronic acid 150 mg once monthly, typically in association with the first dose. Such symptoms were generally of short duration, mild or moderate in intensity, and resolved during continuing treatment without requiring remedial measures. Influenza-like illness includes events reported as acute phase reaction or symptoms including myalgia, arthralgia, fever, chills, fatigue, nausea, loss of appetite, or bone pain.

DRUG INTERACTIONS: *Calcium Supplements & Oral Medications Containing Multivalent Cations:* It is likely that calcium supplements, antacids and some oral medications containing multivalent cations (such as aluminium, magnesium, iron) are likely to interfere with the absorption of Ibandronic acid. Therefore, patients must wait 60 minutes after taking Ibandronic acid before taking other oral medications.Ê*H_2-Receptor Antagonists:* In healthy male volunteers and postmenopausal women, I.V ranitidine caused an increase in ibandronate bioavailability of about 20 %, probably as a result of reduced gastric acidity. However, since this increase is within the normal range of the bioavailability of ibandronate, no dosage adjustment is required when Ibandronic acid is administered with ÊH_2-antagonists or other drugs which increase gastric pH. *Tamoxifen or Hormone Replacement Therapy:* Pharmacokinetic interaction studies in postmenopausal women have demonstrated the absence of any interaction potential with tamoxifen or hormone replacement therapy (oestrogen). *Melphalan/Prednisolone:* No interaction was observed when co-administered with melphalan/prednisolone in patients with multiple myeloma. *Hepatic P450 Isoenzymes:* In relation to disposition, no drug interactions of clinical significance are considered likely, since ibandronate does not inhibit the major human hepatic P450 isoenzymes and has been shown not to induce the hepatic cytochrome P450 system in rats. Furthermore, plasma protein binding is low at therapeutic concentrations and ibandronate is therefore unlikely to displace other drugs.

WARNINGS: *Hypocalcemia:* Hypocalcemia and other disturbances of bone and mineral metabolism should be effectively treated before starting Ibandronic acid therapy. Adequate intake of calcium and vitamin D is important in all patients. *Esophageal Irritation:* Bisphosphonates have been associated with dysphagia, esophagitis and esophageal or gastric ulcers. Therefore, patients should pay particular attention and be able to comply with the dosing instructions. Physicians should be alert to signs or symptoms signaling a possible esophageal reaction during therapy, and patients should be instructed to discontinue Ibandronic acid and seek medical attention if they develop symptoms of esophageal irritation. *Concomitant Administration of NSAIDs:* Since NSAIDs and bisphosphonates are both associated with gastrointestinal irritation, caution should be taken during concomitant medication with Ibandronic acid. *Osteonecrosis:* Osteonecrosis of the jaw has been reported in patients treated with bisphosphonates. 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. *Galactose Intolerance:* Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. *Hepatic Impairment:* No dosage adjustment is necessary. *Patients with Renal Impairment:*ÊNo dosage adjustment is necessary for patients with mild or moderate renal impairment where creatinine clearance is equal or greater than 30 ml/min. Below 30 ml/min creatinine clearance, the decision to administer Ibandronic Acid should be based on an individual risk-benefit assessment. *Elderly:*ÊNo dosage adjustment is necessary. *Pregnancy:* Ibandronic acid should not be used during pregnancy as no adequate data is available. *Lactation:* Ibandronic acid should not be used during lactation as no adequate data is available on humans. *Children:*ÊSafety and efficacy have not been established in patients less than 18 years old.

DOSAGE & ADMINISTRATION: The recommended dose is 1 Osfit 150 mg film-coated tablet once a month. The tablet should preferably be taken on the same date each month. Osfit Tablet should be taken after an overnight fast (at least 6 hours) and 1 hour before the first food or drink (other than water) of the day or any other oral medicinal product or supplementation (including calcium). In case a dose is missed, patients should be instructed to take 1 Osfit 150 mg tablet the morning after the tablet is remembered, unless the time to the next scheduled dose is within 7 days. Patients should then return to taking their dose once a month on their originally scheduled date. If the next scheduled dose is within 7 days, patients should wait until their next dose and then continue taking 1 tablet once a month as originally scheduled. Patients should not take 2 tablets within the same week. Patients should receive supplemental calcium and/or vitamin D if dietary intake is inadequate. *Method of Administration:* Tablet should be swallowed whole with a full glass of plain water (180 to 240 ml) while the patient is sitting or standing in an upright position. Patients should not lie down for 60 minutes after taking Osfit. Plain water is the only drink that should be taken with Osfit. Please note that some mineral water may have a higher concentration of calcium and therefore should not be used. Patients should not chew or suck the tablet because of a potential for oropharyngeal ulceration. *Patients with Hepatic Impairment:* No dose adjustment is required. *Patients with Renal Impairment:* No dose adjustment is necessary for patients with mild or moderate renal impairment where creatinine clearance is equal or greater than 30 ml/min. Osfit is not recommended for patients with a creatinine clearance below 30 ml/min due to limited clinical experience. *Elderly Population:* No dose adjustment is required.

SPECIAL INSTRUCTION TO THE PHYSICIAN: *Overdosage:* No specific information is available on the treatment of over dosage with Ibandronic acid. Oral over-dosage may result in upper gastrointestinal adverse reactions (such as upset stomach, dyspepsia, oesophagitis, gastritis, or ulcer) or hypocalcemia. Milk or antacids should be given to bind Ibandronic acid, and any adverse reactions treated symptomatically. Owing to the risk of oesophageal irritation, vomiting should not be induced and the patient should remain fully upright.

STORAGE/PRECAUTIONS: Protect from moisture, freezing, excessive heat and sunlight. Store below 25 °C. Keep all medicines out of the children's reach.

PRESENTATION: Osfit 150 mg Tablet is available in packing containing 1 film-coated tablet. *Scotmann Specs.

scotmann

Complete Medical Information available only for doctors on request.

Manufactured by: **SCOTMANN PHARMACEUTICALS**
5-D, I-10/3 Industrial Area, Islamabad-Pakistan

اوسفٹ ٹیبلٹ 150 ملی گرام

خوراک :اوسفٹ کی 1 ٹیبلٹ مہینے میں 1 مرتبہ ہے۔ٹیبلٹ کھانے کے لئے مہینے کا وہ دن/تاریخ منتخب کریں جو آپ بآسانی یاد رکھ سکیں، جیسا کہ ہر مہینے کی ایک تاریخ (مثلاً ہر مہینے کی پہلی تاریخ یا ہر مہینے کا ایک ہی دن یا ہر مہینے کا پہلا اتوار)۔اوسفٹ کو ڈاکٹر کی ہدایت کے مطابق مہینے میں ایک مرتبہ باقاعدگی سے استعمال کریں۔اوسفٹ کو دن کے پہلے کھانے/پینے (پانی کے علاوہ) یا کسی اور دوا بالخصوص کیلشیم والی دوا سے 60 منٹ پہلے استعمال کریں۔اوسفٹ سیدھا بیٹھ کر یا سیدھا کھڑے ہو کر ایک گلاس سادہ پانی (منرل واٹر نہیں) کے ساتھ سالم نگلنا چاہیے اور اس کے بعد مزید 60 منٹ تک لیٹنے سے گریز کرنا چاہیے۔یاد رکھیے کہ اوسفٹ صرف سادہ پانی کے ساتھ استعمال کرنی چاہیے کیونکہ منرل واٹر میں کیلشیم موجود ہوسکتا ہے۔اوسفٹ کو چوسنا یا چبانا نہیں چاہیے کیونکہ اس سے حلق اور معدے میں زخم ہوسکتا ہے۔اگر آپ مقررہ دن یا تاریخ پر خوراک لینا بھول جاتے ہیں تو جس دن خوراک لینا یاد آئے اس سے اگلے ہی دن صبح تجویز کردہ طریقہ استعمال کے مطابق اوسفٹ کھا لیجئے۔اگر خوراک میں 7 دن سے کم رہ جائیں تو بھولی ہوئی خوراک نہ لیں بلکہ اگلی مقررہ تاریخ کا انتظار کریں۔حاملہ اور دودھ پلانے والی خواتین کو اوسفٹ استعمال نہیں کرنی چاہیے۔

احتیاط: روشنی، نمی، سخت سردی اور سخت گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔تمام ادویات بچوں کی پہنچ سے دور رکھیں۔صرف مستند ڈاکٹر کے نسخہ پر فروخت اور استعمال کریں۔