

Ibanal Kit

Ibandronic Acid + Calcium Orotate Tablet

Presentation

Ibanal Kit Tablet: Ibanal Kit contains 1 tablet of Ibandronic Acid 150 mg (as Ibandronate Sodium Monohydrate INN) and 60 tablets of Calcium Orotate 400 mg (as Calcium Orotate Dihydrate INN).

Description

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 first line therapy for osteoporosis has been considered to be bisphosphonate and calcium. The sole administration of bisphosphonate reduces bone resorption and facilitates bone mineralization, and calcium is required for bone deposition. Calcium orotate provides maximum therapeutic effect of ibandronic acid and acts as a unique calcium supplement with the functional amino acid chelating ligand orotic acid. The orotic acid and amino acid help in the transport of calcium through cellular membranes increasing the uptake of calcium mainly by osteocytes. Two months of calcium orotate therapy in women with postmenopausal osteoporosis significantly increased serum calcium levels and reduced the symptoms of osteoporosis with no side effects.

Indications

Ibanal Kit is indicated for the:

- Treatment of osteoporosis in women (specially postmenopausal)
- Prevention of osteoporosis in women (specially postmenopausal)
- Prevention and treatment of osteoporosis in men

Dosage and Administration

Dose:

The recommended dose is one 150 mg film-coated tablet once a month. The tablet should preferably be taken on the same date each month. To maximize clinical benefit Ibandronic Acid two tablets of Calcium Orotate 400 mg per day and usually recommended in divided dosage or as directed by physician.

Dosing Instructions:

- To maximize absorption and clinical benefit, Ibandronic Acid tablet of Ibanal Kit should be taken at least 60 minutes before the first food or drink (other than water) of the day or before taking any oral medication or supplementation, including calcium, antacids or vitamins.
- To facilitate delivery to the stomach and thus reduce the potential for esophageal irritation, Ibandronic acid tablet should be swallowed whole with a full glass of plain water (250 ml) while the patient is standing or sitting in an upright position. Patients should not lie down for 60 minutes after taking Ibandronic acid tablet.
- Patients should not eat drink anything except water or take any medications at least for 60 minutes after taking Ibandronic acid tablet.
- Plain water is the only drink that should be taken with Ibandronic acid tablet. Note that some mineral waters have higher concentration of calcium and therefore should not be used.
- Patients should not chew, crush or let the tablet dissolve in mouths because of a potential for oropharyngeal ulceration.
- Ibandronic acid 150 mg tablet of Ibanal kit should be taken on the same date of each month (i.e. the patient's Ibandronic acid day).
- The patients must not take two Ibandronic acid 150 mg tablets within the same week.
- If the once-monthly dose is missed, and the patients next scheduled Ibandronic acid day is more than 7 days away the patient should be instructed to take one Ibandronic Acid 150 mg tablet in the morning following the date that it is remembered. The patient should then return to taking one Ibandronic acid 150 mg tablet every month in the morning of their chosen day, according to their original schedule.

Side Effects

Ibandronic Acid

Common adverse reactions include dyspepsia, nausea, diarrhea, constipation, abdominal pain, myalgia, headache, mild flu-like symptoms, dizziness, skin rash.

Calcium orotate

Bloating and swelling in the abdomen are common side effects of Calcium Orotate. Loss of appetite, constipation, nausea, vomiting, unusual weight loss, headache and increased thirst/urination, Formation of kidney stones may occur infrequently.

Precautions

Ibandronic Acid

Hypocalcaemia must be corrected before starting Ibandronic Acid therapy. Other disturbances of bone and mineral metabolism should also be effectively treated. Adequate intake of calcium and vitamin D is important in all patients.

Bisphosphonates have been associated with dysphagia, oesophagitis and oesophageal or gastric ulcers. Therefore patients, especially those with a history of prolonged oesophageal transit time, should pay particular attention to and be able to comply with the dosing instructions. Physicians should be alert to signs or symptoms signaling a possible oesophageal reaction during therapy, and patients should be instructed to discontinue Ibandronic Acid and seek medical attention if they develop symptoms of oesophageal irritation such as new or worsening dysphagia, pain on swallowing, retrosternal pain, or heartburn. Since NSAIDs and bisphosphonates are both associated with gastrointestinal irritation, caution should be taken during concomitant administration.

Due to limited clinical experience, Ibandronic Acid is not recommended for patients with a creatinine clearance below 30 ml/min.

Calcium Orotate

Before taking calcium, precaution is needed if the patient has any allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Precaution is needed before using this product in kidney disease, kidney stones, little or no stomach acid (achlorhydria), heart disease, disease of the pancreas, a certain lung disease(sarcoidosis), difficulty absorbing nutrition from food (mal-absorption syndrome).

Use in Pregnancy & Lactation

Pregnancy:

There are no adequate data from the use of Ibanal Kit in pregnant women. Ibanal Kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. The potential risk for humans is unknown.

Pregnancy Category of Ibandronic Acid: C

Lactation

It is not known whether Ibanal Kit is excreted in human milk.

Ibanal Kit should be used with caution during lactation.

Contraindications

Ibandronic Acid

- Hypocalcaemia
- Known Hypersensitivity to Ibandronic acid
- Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 60 minutes

Calcium Orotate

Calcium Orotate is contraindicated in conditions like kidney stone, kidney disease and increased activity of the parathyroid gland, high amount of Calcium in urine & blood and extreme loss of body water.

Overdose

No specific information is available on the treatment of overdose with Ibanal Kit. However overdose may result in hypocalcaemia, hypophosphatemia, upset stomach, dyspepsia, esophagitis & gastritis.

Drug Interactions

Ibandronic Acid

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 Ibandronic Acid before taking other oral medications.

Calcium Orotate

Calcium can decrease absorption of the following drugs when taken together with bisphosphonates, quinolone antibiotics, tetracycline antibiotics, levothyroxine, phenytoin and tiludronate disodium. Thiazide-type diuretics can interact with Calcium supplements, increasing the risks of hypercalcemia and hypercalciuria.

Storage Conditions

Store in a cool and dry place, away from light. Keep out of reach of the children.

Commercial Pack

Ibanal Kit: Each box contains one Kit. Each Kit contains 1 film coated tablet of Ibandronic Acid 150 mg and 60 film coated tablets of Calcium Orotate 400 mg in one calendar strip.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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