

# Bonestar kit

1 Tablet of Ibandronic Acid 150 mg & 60 Tablets of Calcium Orotate 400 mg

## COMPOSITION

Each kit contains 1 film coated tablet of Ibandronate Sodium Monohydrate INN equivalent to Ibandronic Acid 150 mg and 60 film coated tablets of Calcium Orotate Dihydrate INN equivalent to Calcium Orotate 400 mg.

## PHARMACOLOGY

Ibandronic Acid is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The action of Ibandronic Acid on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone. It 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

This kit is indicated for the treatment and prevention of osteoporosis in postmenopausal women. It increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.

## DOSAGE AND ADMINISTRATION

One tablet of Ibandronic Acid 150 mg tablet taken once monthly on the same date of each month is recommended. Two tablets of Calcium Orotate 400 mg per day are usually recommended in divided dosage or as directed by physicians.

### Dosing instructions

- To maximize absorption and clinical benefit, Ibandronic Acid of this 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 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 other medications for at least 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 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.
- Ibandronic Acid 150 mg tablet should be taken on the same date of each month (i.e., the patient's Ibandronic Acid day).
- The patient must not take two 150 mg tablets within the same week.
- If the once-monthly dose is missed, and the patient's 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.
- If the once-monthly dose is missed, and the patient's next scheduled Ibandronic Acid day is only 1 to 7 days away, the patient must wait until the subsequent month's scheduled Ibandronic Acid day to take their tablet. 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.
- Start taking Calcium Orotate tablets from the next day of Ibandronic Acid day (from 'Day 2' and onwards)

### Recommendations for Calcium supplementation

Patients should receive supplemental Calcium (already provided as Calcium Orotate 400 mg tablet) if dietary intake is inadequate.

## CONTRAINDICATIONS

Ibandronic Acid is contraindicated in conditions like,

- Abnormalities of the esophagus which delay esophageal emptying.
- Inability to stand or sit upright for at least 60 minutes.
- Hypocalcemia.
- Known hypersensitivity to Ibandronic Acid or to any of its excipients.

Calcium Orotate is contraindicated in conditions like,

- Kidney stone, Kidney disease.
- Sarcoidosis.
- Increased activity of the parathyroid gland.

## WARNING AND PRECAUTION

### Ibandronic Acid

#### Upper Gastrointestinal Adverse Reactions

Ibandronic Acid may cause local irritation of the upper gastrointestinal mucosa.

#### Hypocalcemia and Mineral Metabolism

Treat hypocalcemia and other disturbances of bone and mineral metabolism before starting Ibandronic Acid 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 Ibandronic Acid. Consider discontinuing use if severe symptoms develop.

#### Severe Renal Impairment

Ibandronic Acid is not recommended for use in patients with severe renal impairment (creatinine clearance of <30 mL/min).

### Calcium Orotate

Before taking Calcium Orotate, precaution is needed if the patient has any allergies. Any Calcium supplement taken without food may increase the risk of kidney stones.

## SIDE EFFECTS

### Ibandronic Acid

Common side effects include Hypertension, Dyspepsia, Nausea, Diarrhea, Abdominal Pain, Arthralgia, Back Pain, Localized Osteoarthritis, Myalgia, Muscle Cramp, Influenza, Nasopharyngitis, Bronchitis, Urinary Tract Infection, Headache, Dizziness, Skin Rash, Insomnia etc.

### Calcium Orotate

Common side effects include Bloating, Constipation, formation of kidney stones may occur infrequently.

## DRUG INTERACTION

### Ibandronic Acid

#### Calcium Supplements/Antacids

Products containing Calcium and other multivalent cations (such as Aluminium, Magnesium, Iron) are likely to interfere with absorption of Ibandronic Acid.

#### Aspirin/Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Aspirin, NSAIDs and bisphosphonates are all associated with gastrointestinal irritation, caution should be exercised in the concomitant use of Aspirin or NSAIDs with Ibandronic Acid.

### Calcium Orotate

Calcium can decrease absorption of the following drugs when taken together: Biphosphate (e.g., Alendronate), Quinolone antibiotics (e.g., Doxycycline, Minocycline), Levothyroxine, Phenytoin (an anticonvulsant), and Tiludronate Disodium (to treat Paget's disease). Thiazide-type diuretics can interact with Calcium supplements, increasing the risks of hypercalcemia and hypercalciuria.

## USE IN PREGNANCY & LACTATION

There are no adequate and well controlled studies in pregnant women for this kit. This kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. It is not known whether this Kit is excreted in human milk. Caution should be exercised when this Kit is administered to a nursing woman.

## USE IN CHILDREN & ADOLESCENTS

There is no relevant use of Ibandronic Acid in children below 18 years, and Ibandronic Acid was not studied in this population.

## OVER DOSAGE

No specific information is available on the treatment of overdosage of Ibandronic Acid. Prolonged use of Calcium with high doses can lead to hypercalcemia.

## STORAGE

Keep below 30°C temperature, protected from light and moisture. Keep out of the reach of children.

## HOW SUPPLIED

Each box contains one kit in Alu-PVDC blister pack where the kit contains 1 film coated tablet of Ibandronate Sodium Monohydrate INN equivalent to Ibandronic Acid 150 mg and 60 film coated tablets of Calcium Orotate Dihydrate INN equivalent to Calcium Orotate 400 mg in one calendar strip.