

# MarinCal<sup>TM</sup> Kit

1 tablet of Ibandronic Acid 150 mg & 60 tablets of Calcium 500 mg (coral source) & Vitamin-D<sub>3</sub> 200 IU



## Presentation

MarinCal<sup>TM</sup> Kit: Each kit contains 1 tablet of Ibandronic Acid (Each film coated tablet contains Ibandronate Sodium Monohydrate INN eq. to Ibandronic Acid 150 mg) and 60 tablets of Calcium (Coral Source) and Vitamin D (Each tablet contains Calcium Carbonate (Coral Source) BP eq. to elemental Calcium 500 mg and Vitamin D<sub>3</sub> 200 IU as Colecalciferol BP)

## Description

### Ibandronic Acid

Ibandronic Acid (Ibandronate Sodium Monohydrate) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. The action of Ibandronate on bone tissue is based on its affinity for hydroxyapatite, which is 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.

### Calcium (Coral) and Vitamin-D

The combination of Coral Calcium and Colecalciferol is composed of Calcium Carbonate with small amounts of Magnesium and other Trace minerals. Coral Calcium ensures better absorption than Calcium of other Calcium Carbonate origin due to its chemical structure that is very similar to the composition of human bone Calcium Carbonate. Vitamin-D aids in the absorption of Calcium from GI tract and helps to maintain Calcium balance in the body.

## Indications and Usage

MarinCal Kit is indicated for the treatment and prevention of osteoporosis.

## Dosage and Administration

Dose: One tablet of Ibandronic Acid 150 mg once monthly on the same date of each month is recommended. To maximize clinical benefit of Ibandronic acid, two tablets of Calcium (Coral Source) 500 mg and Vitamin D 200 IU per day are usually recommended in divided dosage or as directed by the physician.

## Dosing Instructions

### Day 1:

- Take the Ibandronic Acid tablet (as mentioned 'Day1' on the strip) on an empty stomach 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, Antacid and/ or Vitamins
- Swallow tablet whole with a glass of plain water while standing or sitting in an upright position
- Avoid lying down for 60 minutes
- Do not chew or suck the tablet

### Day 2 -31:

- One tablet of Calcium and Vitamin D should be taken at the morning and at the evening after meal
- Tablets should be taken in order as directed on the blister strip for ease of dose tracking

## Side-effects

- Pain or trouble with swallowing
- Constipation
- Chest pain
- Diarrhea
- Heartburn (esophagitis)
- Pain in extremities (arms or legs)
- Flatulence
- Dyspepsia (upset stomach)
- Allergic reaction

## Contraindications

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

## Precaution

### Ibandronic Acid

- **Upper Gastrointestinal Adverse Reactions:** Ibandronic acid like other bisphosphonates administered orally may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects, caution should be used when Ibandronic acid is given to patients with active upper gastrointestinal problems (such as known Barrett's esophagus, dysphagia, other esophageal diseases, gastritis, duodenitis or ulcers).
- **Hypocalcaemia and Mineral Metabolism:** Treat hypocalcemia and other disturbances of bone and mineral metabolism before starting therapy.
- **Musculoskeletal Pain:** Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Ibandronic acid and other bisphosphonates.
- **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.

### Calcium (Coral) and Vitamin-D

In mild hypercalciuria reduction of dose is sufficient to return to normal serum Calcium concentration. Plasma and serum Calcium level should be monitored in mild to moderate renal impairment patients and also in case of long term use. Patients with renal stone or with such previous history should be recommended to increase their fluid intake.

## Use in specific populations

**Pregnancy:** Pregnancy category-C. There are no adequate and well-controlled studies in pregnant women. MarinCal kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

**Nursing mother:** It is not known whether MarinCal kit is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when MarinCal kit is administered to a nursing woman.

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

## Drug Interactions

### Ibandronic Acid

Products containing calcium and other multivalent cations (such as aluminum, magnesium, iron), including milk, food, and antacids are likely to interfere with absorption of Ibandronate. It is also found to interact with H<sub>2</sub> blockers such as Ranitidine in several clinical trials.

### Calcium (Coral) and Vitamin-D

Oral Calcium can reduce the absorption of tetracycline & fluoride preparations and minimum 3 hours' time should be allowed between ingestion of these medications. Thiazide diuretics reduce the renal excretion of Calcium. Phenytoin, barbiturates, glucocorticoids may induce metabolism of Vitamin D. Concomitant intake of certain foods like spinach, cereals, milk and its derivatives may reduce the intestinal uptake of Calcium.

## Over dosage

No specific information is available on the treatment of over dosage of Ibandronic acid. However, based on knowledge of this class of compounds, oral over dosage may result in hypocalcemia, hypophosphatemia, and upper gastrointestinal adverse events.

## Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial Pack

MarinCal<sup>TM</sup> Kit: Each box contains 1 blister strip of 61 tablets containing 1 film coated tablet of Ibandronic Acid 150 mg and 60 tablets of Calcium (coral source) 500 mg and Vitamin-D<sub>3</sub> 200 IU.

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