

# Calcoral kit

Ibandronic Acid & Calcium (Coral) + Vitamin D<sub>3</sub>

## Presentation

Calcoral kit: Each kit contains 1 Ibandronic Acid Tablet and 30 Tablets of Calcium + Vitamin D<sub>3</sub>. Each Ibandronic Acid Tablet contains 168.75 mg Ibandronate Sodium INN equivalent to 150 mg Ibandronic Acid and each Calcium + Vitamin D<sub>3</sub> Tablet contains 1500 mg Calcium Carbonate (derived from Coral source) BP equivalent to 600 mg Calcium & 400 IU Vitamin D<sub>3</sub> BP (Cholecalciferol).

## Indications

Calcoral kit is indicated for the treatment and prevention of Osteoporosis. It increases Bone Mineral Density (BMD) and reduces the incidence of vertebral fractures.

## 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 benefits of Ibandronic acid, one tablets of Calcium (Coral) 600 mg & Vitamin D<sub>3</sub> 400 IU per day is usually recommended with. 150 mg Ibandronic Acid.

## Dosing Instructions

To maximize absorption and clinical benefit, Ibandronic Acid tablet of Calcoral 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 shifting 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. Patients should not chew, crush or let the tablet dissolve in mouth because of the potential risk for oropharyngeal ulceration. Ibandronic Acid 150 mg tablet of Calcoral Kit should be taken on the same date of each month. The patient must not take two Ibandronic Acid 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. Start taking Calcium (Coral) & Vitamin D<sub>3</sub> 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 Coral Calcium & Vitamin D<sub>3</sub> tablet) if dietary intake is inadequate.

## **Contraindications**

Ibandronic Acid is contraindicated in conditions like: abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia. Inability to stand or sit upright for at least 60 minutes, Hypocalcemia, known hypersensitivity to Ibandronic Acid. Calcium & Vitamin D<sub>3</sub>: Hypersensitivity to any of the component of this preparation. It is also contraindicated in case of hypercalcemia, hyperparathyroidism, hypercalciuria, nephrolithiasis, severe renal insufficiencies, concomitant Digoxin therapy (requires careful monitoring of serum calcium level), renal calculi and Zollinger-Ellison syndrome.

## **Precautions**

**Ibandronic Acid: Upper Gastrointestinal Adverse Reactions** Ibandronic Acid of Calcoral kit may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects and a potential for worsening of the underlying disease, 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). The risk of severe esophageal adverse experiences appears to be greater in patients who lie down after taking oral bisphosphonates and/or who fail to swallow it with the recommended full glass (250 ml) of water, and/or who continue to take oral bisphosphonates after developing symptoms suggestive of esophageal irritation. There have been post-marketing reports of gastric and duodenal ulcers with oral bisphosphonate use, some severe and with complications, although no increased risk was observed in controlled clinical trials.

**Hypocalcemia and Mineral Metabolism:** Adequate intake of calcium 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 the 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 & Vitamin D<sub>3</sub>:** Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully and periodic checks of plasma Calcium levels and urinary Calcium excretion should be made. Calcium should be used cautiously in patients with pre-existing heart disease, sarcoidosis, kidney stones and kidney diseases. Calcium carbonate containing products reduce acidity of the stomach. When hypercalcemia occurs, discontinuation of the drug is usually sufficient to return serum Calcium concentrations to normal. Patients with a history of stone formation should also be recommended to increase their fluid intake.

## **Drug Interactions**

**Ibandronic Acid: Calcium Supplements/Antacids,** Products containing calcium and other multivalent cations (such as aluminum, magnesium, iron) are likely to interfere with absorption of Ibandronic Acid. Ibandronic Acid 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) and bisphosphonates are all associated with gastrointestinal irritation. So caution should be exercised in the concomitant use of aspirin or NSAIDs with Ibandronic Acid. H<sub>2</sub> Blocker in healthy volunteers, co-administration with ranitidine resulted in a 20% increased bioavailability of Ibandronic Acid, which was not considered to be clinically relevant.

Calcium & Vitamin D<sub>3</sub>: It has possible interaction with Digoxin, antacids containing Calcium, Aluminum or Magnesium, other Calcium supplements, Calcitriol. Oral calcium can reduce the absorption of Tetracycline, Doxycycline, Aminocycline or Oxytetracycline; therefore, minimum 3 hours time should be allowed between ingestion of these medications. Thiazide diuretics reduces the renal excretion of Calcium. Phenytoin, Barbiturates, Glucocorticoids may induce metabolism of Vitamin D<sub>3</sub>. Concomitant ingestion of certain foods like spinach, cereals, milk and its derivatives may reduce the intestinal uptake of Calcium. So while taking Calcium (from Coral source) and Vitamin D<sub>3</sub> with any of these drugs consultations of the physicians is needed.

### **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, Upper Respiratory Tract Infection, Headache, Dizziness, Skin rash, Insomnia etc. Calcium & Vitamin D<sub>3</sub>: Most common side effects are flatulence, diarrhea, constipation, upper GI discomfort etc. Hypercalciuria and hypercalcemia due to prolong use has rarely been reported.

### **Use in Specific Population**

Pregnancy: There are no adequate and well-controlled studies in pregnant women for Calcoral kit. This kit should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus. Pregnancy Category of Ibandronic Acid: C. Nursing Mothers: It is not known whether is excreted in human milk. Caution should be exercised when Calcoral kit is administered to a nursing woman. Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

### **Pharmaceutical Precautions**

Store at below 30°C in a dry place, protected from light. Keep out of reach of children.

### **Commercial Pack**

**Calcoral kit:** Each box contains one kit.

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