BARON® TABLETS

Composition:
Each film coated tablet contains: Ibandronate sodium monohydrate equivalent to Ibandronic acid 150mg.
Pharmacology:
Ibandronic acid is a highly potent bisphosphonate belonging to the nitrogen-containing group of bisphosphonates, which act selectively on bone tissue and specifically inhibit osteoclast activity without directly affecting bone formation. In vivo, ibandronic acid prevents experimentally induced bone destruction caused by cessation of gonadal function, retinoids, tumours or tumour extracts.
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. 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 approximately 85 - 87% (determined *in vitro* at therapeutic concentrations), and thus there is a low potential for interaction with other medicinal products due to displacement
Biotransformation: There is no evidence that ibandronic acid is metabolized in animals or humans.
Elimination: The absorbed fraction of ibandronic acid is removed from the circulation via bone absorption (estimated to be 40 - 50% in postmenopausal women) and the remainder is eliminated unchanged by the kidney. The unabsorbed fraction of ibandronic acid is eliminated unchanged in the faeces. The range of observed apparent half-lives is broad; the apparent terminal half-life is generally in the range of 10 - 72 hours. As the values calculated are largely a function of the duration of study, the dose used, and assay sensitivity, the true terminal half-life is likely to be substantially longer, in common with other bisphosphonates.
Indications:
Treatment of osteoporosis in postmenopausal women at increased risk of fracture.
A reduction in the risk of vertebral fractures has been demonstrated; efficacy on femoral neck fractures has not been established.
Dosage & Administration:
Method of administration: For oral use.
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. Ibandronic acid 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 products or supplementation (including calcium).
Contraindications:
- Hypersensitivity to ibandronic acid or to any of the excipients.
- Hypocalcaemia.
- Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia.
- Inability to stand or sit upright for at least 60 minutes.

Side Effects:
Common adverse effect includes; Headache, Oesophagitis, Gastritis, Gastro oesophageal reflux disease, Dyspepsia, Diarrhoea, Abdominal pain, Nausea and Rashes. Other include Arthralgia, Myalgia, Musculoskeletal pain, Muscle cramp, musculoskeletal stiffness and Influenza like illness.
Uncommon adverse effect include: Fatigue, back pain oesophagitis including oesophageal ulcerations or strictures and dysphagia, vomiting and flatulence.
Drug interactions:
Oral bioavailability of Ibandronic acid is generally reduced in the presence of food. In particular, products containing calcium, including milk, and other multivalent cations (such as aluminium, magnesium, iron), are likely to interfere with absorption of ibandronic acid. Metabolic interactions are not considered likely, since ibandronic acid does not inhibit the major human hepatic P450 isoenzymes.
NSAIDs and bisphosphonates are associated with gastrointestinal irritation; caution should be taken during concomitant administration.
Pregnancy and lactation:
Ibandronic acid is only for use in postmenopausal women and must not be taken by women of childbearing potential.
Ibandronic acid should not be used during breast-feeding.
In reproductive studies in rats by the oral route, ibandronic acid decreased fertility
Overdosage:
Oral overdose may result in upper gastrointestinal adverse reactions (such as upset stomach, dyspepsia, oesophagitis, gastritis, or ulcer) or hypocalcaemia. 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.
Presentation:
Blister pack of one tablet per unit box.
Storage conditions:
Store in a cool, dry place below 30°C. Protect from light.
Keep all medicines out of reach of children.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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Ref: Lf /DL/BARON/01 Date of issue: November 2016