ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of RHEUMATOLOGY PROFESSIONALS

The Interprofessional Division of the American College of Rheumatology

Ibandronate (Boniva®)

Ibandronate is a bisphosphonate prescribed to prevent or treat osteoporosis in women after menopause. Bone is a living tissue constantly being remodeled. Bisphosphonates specifically act on bone cells (osteoclasts) to inhibit bone resorption and turnover activity and reduce progressive bone loss and risk for fracture.

Resources from Manufacturer

Patient Medication Guide (tablets)

Full Prescribing Information (tablets)

Patient Medication Guide (injection)

Full Prescribing Information (injection)

FDA-Approved Indications and Dosing in Rheumatology

Ibandronate is indicated for:

■ Treatment and prevention of osteoporosis in postmenopausal women (prevention only for tablets)

Oral Dosing

Osteoporosis: 150mg once monthly.

Intravenous Dosing

■ Osteoporosis: 3 mg once every 3 months. This is administered intravenously over 15-30 seconds.

Contraindications

Known hypersensitivity to ibandronate or excipients, uncorrected hypocalcemia, abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia, inability to stand or sit upright for at least 60 minutes (oral only)

Warnings and Precautions

- 1. Hypocalcemia: Must be corrected before initiating ibandronate. Hypocalcemia may worsen, especially in patients with renal impairment. Adequately supplement patients with calcium and vitamin D.
- 2. Anaphylaxis has been reported
- 3. Caution with renal impairment (do not administer in patients with creatinine clearance less than 30 mL/min)
- 4. Tissue damage with inappropriate drug administration can occur
- 5. Severe bone, joint and/or muscle pain may occur.
- 6. Pregnancy
- 7. Osteonecrosis of the jaw (ONJ) has been reported with ibandronate monitor for symptoms.
- 8. Atypical femoral fractures have been reported. Evaluate patients with thigh or groin pain for femoral fracture

ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of RHEUMATOLOGY PROFESSIONALS

The Interprofessional Division of the American College of Rheumatology

Adverse Reactions (>5%)

- Back pain
- Dyspepsia
- Pain in extremity
- Diarrhea
- Headache
- Myalqia

Medication Strength and Preparations

- Oral tablets: Store at 25°C (77°F); excursions permitted between 15° and 30°C
- IV Solution: Store at 25°C (77°F); excursions permitted between 15° and 30°C

Oral Administration

- 1. Take ibandronate 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 maximize absorption
- 2. Avoid the use of water with supplements including mineral water because they may have a higher concentration of calcium.
- 3. Swallow ibandronate tablets whole with a full glass of plain water (6 to 8 oz) while standing or sitting in an upright position to reduce the potential for esophageal irritation. Avoid lying down for 60 minutes after taking
- 4. Do not chew or suck the tablet because of a potential for oropharyngeal ulceration.
- 5. Do not eat, drink anything except plain water, or take other medications for at least 60 minutes after taking

Intravenous Administration

- 1. Ibandronate injection must be administered by a healthcare professional.
- 2. Remove prefilled syringe of ibandronate sodium injection, 3 mg/3 mL single-use, clear glass prefilled syringe and attach provided 25-gauge, ¾ inch butterfly needle, and attach plastic tubing to barrel.
- 3. Visually inspect the liquid in the prefilled syringe for particulate matter and discoloration before administration. Do not use prefilled syringes with particulate matter or discoloration.
- 4. Administer only with the enclosed needle.
- 5. Do not mix with calcium-containing solutions or other intravenously administered drugs.
- 6. Administer in a 15 to 30 second IV bolus using the prefilled syringe which contains 1mg/ml (3 mg total) of ibandronate.
- 7. Discard any unused portion.

ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of RHEUMATOLOGY PROFESSIONALS

The Interprofessional Division of the American College of Rheumatology

Intravenous Administration Pre-infusion Checklist

- 1. Check to ensure that a creatinine clearance has been performed within two weeks of the infusion, and that creatinine clearance is greater than 30 mL per minute.
- 2. Calcium level must be within normal range

Updated June 2023–ARP Practice Committee

DISCLAIMER: The information contained in this biologic reference guide is published by the American College of Rheumatology ["ACR"] for informational purposes only, in furtherance of its educational mission. It is not a substitute for user's independent medical discretion or decision making, nor a replacement for the manufacturer's complete prescribing and labeling information, as in effect at the time of use. The information contained herein reflects the conclusions of the individual companies who manufacture the products and not those of the ACR. ACR does not endorse or make any statement regarding the efficacy or safety of any of the listed companies or any of their drugs or other products. ACR specifically disclaims any and all responsibility or liability for the accuracy or completeness of the contents of this reference guide, the use of such information by anyone and/or for the performance of any of the drugs listed in this biologic reference guide (including without limitation, any adverse effects).