ACR/ARP Medication Guide

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Alendronate (Fosamax®)

Alendronate is a bisphosphonate prescribed to prevent or treat osteoporosis in men and women after menopause, as well as gluco-corticoid infused osteoporosis. 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

<u>Patient Medication Guide</u> Full Prescribing Information

FDA-Approved Indications and Dosing in Rheumatology

Alendronate is indicated for:

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment to increase bone mass in men with osteoporosis
- Treatment of glucocorticoid-induced osteoporosis
- Treatment of Paget's disease of bone

Oral Dosing

- Treatment dosing: 70mg once weekly as a single tablet
- Prevention dosing: 35mg once weekly as a single tablet
- Calcium and Vitamin D supplements are also recommended

Contraindications

Abnormalities of the esophagus which delay emptying such as stricture or achalasia, inability to stand/sit upright for at least 30 minutes, do not administer FOSAMAX oral solution to patients at increased risk of aspiration, hypocalcemia, hypersensitivity to any component of this product

Warnings and Precautions

- 1. Severe irritation of upper gastrointestinal (GI) mucosa can occur. Follow dosing instructions. Use caution in patients with active upper GI disease. Discontinue if new or worsening symptoms occur
- 2. Hypocalcemia: Must be corrected before initiating ibandronate. Hypocalcemia may worsen, especially in patients with renal impairment. Adequately supplement patients with calcium and vitamin D.
- 3. Caution with renal impairment (do not administer in patients with creatinine clearance less than 35 mL/min)
- 4. Severe bone, joint and/or muscle pain may occur.

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Warnings and Precautions continued

- 5. Pregnancy
- 6. Osteonecrosis of the jaw (ONJ) has been reported with ibandronate (same class as alendronate) –monitor for symptoms.
- 7. Atypical femoral fractures have been reported. Evaluate patients with thigh or groin pain for femoral fracture.

Adverse Reactions (≥3%)

- Abdominal pain
- Acid regurgitation
- Constipation
- Diarrhea
- Dyspepsia
- Musculoskeletal pain
- Nausea

Medication Strength and Preparations

Available as 5mg, 10mg, 35mg, 40mg, and 70 mg tablets

Medication Administration and Storage

■ Tablets should be stored at room temperature between 59 to 86° F

Oral Administration

- Administer first thing in the morning, and at least 30 minutes before food and other medications
- Must be taken with 6-8 oz of plain water, tablet should be swallowed whole.
- Patients must be instructed to stay upright (not lie down) for at least 30 minutes after dose, and until at least first meal of the day
- Oral solution should be followed by at least 2 oz of water

Updated June 2023–ARP Practice Committee

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