ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

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The Interprofessional Division of the
American College of Rheumatology

Risedronate (Actonel®)

Risedronate is a bisphosphonate prescribed to prevent or treat osteoporosis in men and post-menopausal women. 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> <u>Full Prescribing Information</u>

FDA-Approved Indications and Dosing in Rheumatology

Risedronate is indicated for:

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

Oral Dosing

- Treatment of Osteoporosis in Postmenopausal Women: 5 mg daily, 35 mg once a week, 75 mg taken on two consecutive days each month, or 150 mg once a month
- Prevention of Osteoporosis in Postmenopausal Women: 5 mg daily, or 35 mg once a week
- Men with Osteoporosis: 35 mg once a week
- Treatment and Prevention of Glucocorticoid-Induced Osteoporosis: 5 mg daily
- Paget's Disease: 30 mg daily for 2 months

Contraindications

Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia, inability to stand or sit upright for at least 30 minutes, hypocalcemia, known hypersensitivity to any component of this product

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Warnings and Precautions

- 1. Products Containing Same Active Ingredient: Patients receiving Atelvia® should not be treated with Actonel
- 2. Upper Gastrointestinal Adverse Reactions can occur. Instruct patients to follow dosing instructions. Discontinue use if new or worsening symptoms occur
- 3. Hypocalcemia may worsen and must be corrected prior to use
- 4. Osteonecrosis of the Jaw has been reported
- 5. Severe Bone, Joint, Muscle Pain may occur. Discontinue use if severe symptoms develop
- 6. Atypical Femur Fractures have been reported. Patients with new thigh or groin pain should be evaluated to rule out a femoral fracture

Adverse Reactions (≥10%)

- Back pain
- Arthralgia
- Abdominal pain
- Dyspepsia
- Hypersensitivity reactions (angioedema, generalized rash, bullous skin reactions, Stevens-Johnson syndrome, and toxic epidermal necrolysis), and eye inflammation (iritis, uveitis) have been reported rarely

Medication Strength and Preparations

Available as 5mg, 30mg, 35mg, and 150mg tablets

Medication Administration and Storage

- Medication Administration and Storage
- Store at controlled room temperature 20° to 25° C (68° to 77° F)

Oral Administration

- Swallow tablet whole with 6 to 8 ounces of plain water, at least 30 minutes before the first food, beverage, or medication of the day
- Avoid lying down for 30 minutes
- Take supplemental calcium and vitamin D if dietary intake is inadequate

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