

FDA Approvals: Remicade and Actonel **CME/CE**

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Disclosures

To earn CME credit, read the news brief along with the CME information that follows and answer the test questions.

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Credits Available

Physicians - maximum of 0.25 *AMA PRA Category 1 Credit(s)*[™] for physicians;

Family Physicians - up to 0.25 AAFP Prescribed credit(s) for physicians;

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August 17, 2006 — The US Food and Drug Administration (FDA) has approved an expanded indication for infliximab injection in patients with psoriatic arthritis; and a new indication for risedronate for men with osteoporosis.

Risedronate Sodium (Actonel) Once-Weekly Therapy for Osteoporosis in Men

On August 11, the FDA approved a new indication for once-weekly risedronate sodium 35-mg tablets (*Actonel*, made by Proctor & Gamble Pharmaceuticals, Inc), allowing their use for increasing bone mass in men with osteoporosis.

The approval was based on data from a 2-year, double-blind, placebo-controlled, multinational study in 285 men with osteoporosis (mean age, 60.6 years; range, 36 - 84 years; 95% white). All patients had either a bone mineral density (BMD) T-score of -2 or less at the femoral neck and -1 or less at the femoral spine or a BMD T-score of -1 or less at the femoral neck and -2.5 or less at the lumbar spine (mean lumbar spine and femoral neck T-scores, -3.21 and -2.38, respectively).

Patients were randomized to receive either risedronate 35 mg weekly (n = 191) or placebo (n = 93) in addition to daily supplementation with 1000 mg of calcium and 400 to 500 IU of vitamin D.

Results at 2 years showed that weekly administration of risedronate yielded significant mean increases vs placebo in BMD at the lumbar spine (4.5%), femoral neck (1.1%), trochanter (2.2%), and total proximal femur (1.5%).

The overall safety and tolerability of risedronate in men was similar to that reported in postmenopausal osteoporosis clinical trials, with constipation, back pain, arthralgia, influenza, and nasopharyngitis occurring most frequently. Increased rates for benign prostatic hyperplasia (5% vs placebo, 3%), nephrolithiasis (3% vs 0%), and arrhythmia (2% vs 0%) were also reported.

To reduce the risk for gastrointestinal disorders, risedronate should be taken in an upright position with a full glass of water at least 30 minutes prior to the first food or drink of the day. A missed dose should be taken on the following morning, with subsequent resumption of the original weekly schedule; no more than 1 tablet should be taken daily.

Risedronate 35-mg tablets previously were approved for once-weekly use in the prevention and treatment of osteoporosis in postmenopausal women; the 5-mg tablets may also be taken once daily for this indication and for the treatment and prevention of glucocorticoid-induced osteoporosis in men and women. A 30-mg tablet is also available for once-daily administration for a 2-month period in the treatment of Paget's disease.

<http://www.fda.gov/cder/whatsnew.htm>

Learning Objectives for This Educational Activity

Upon completion of this activity, participants will be able to:

- Describe the data that led to an expanded indication for infliximab in the treatment of psoriatic arthritis.
- Identify the benefits of risedronate therapy for osteoporosis in men.
- Explain the appropriate use and potential adverse events related to use of risedronate in men.

Pearls for Practice

- The FDA has approved an expanded indication for infliximab injection in psoriatic arthritis, allowing its use for reducing the progression of structural damage and improving physical function in addition to reducing signs and symptoms of active disease. The approval was based on data showing that infliximab therapy yielded significant reductions in radiographic

progression of structural damage at 24 weeks, relative to placebo (van der Heijde-Sharp scores, -0.7 vs 0.82; $P < .001$); this benefit was maintained at 1 year. Also, 42% and 48% of infliximab-treated patients achieved a 90% improvement from baseline in the skin component of the disease (Psoriasis Area Severity Index 90) at 1 and 2 years. Infliximab was also linked to significant improvements in physical function and ability to perform activities of daily living within 2 weeks of initiation, with responses sustained for a 2-year study period. The recommended dose of infliximab for psoriatic arthritis is 5 mg/kg administered as an initial intravenous infusion, followed by additional similar doses at 2 and 6 weeks and then every 8 weeks thereafter. Infliximab can be used with or without methotrexate.

- Once-weekly risedronate sodium 35-mg tablets have been approved for increasing bone mass in men with osteoporosis. The approval was based on study data showing that risedronate therapy yielded significant mean increases vs placebo in bone mineral density at the lumbar spine (4.5%), femoral neck (1.1%), trochanter (2.2%), and total proximal femur (1.5%) at 2 years.
- The overall safety and tolerability of risedronate in men was similar to that reported in postmenopausal osteoporosis clinical trials, with constipation, back pain, arthralgia, influenza, and nasopharyngitis most commonly reported. Additional events included benign prostatic hyperplasia (5%), nephrolithiasis (3%), and arrhythmia (2%). To reduce the risk for gastrointestinal disorders, risedronate should be taken in an upright position with a full glass of water at least 30 minutes prior to the first food or drink of the day. A missed dose should be taken on the following morning, with subsequent resumption of the original weekly schedule; no more than 1 tablet should be taken daily.