In the treatment of postmenopausal osteoporosis

The proven fracture protection of Actonel, now available in a Once-a-Month tablet[1]

Introducing…

NDC Number 0149-0478-01

WAC: $83.46[2]

Actonel 150 mg, for Once-a-Month dosing.

Actonel 150 mg is available from the manufacturer at the same price as the average daily cost of Actonel 35 mg Once-a-Week.[2]

- Actonel 150 mg Once-a-Month was shown to be therapeutically similar to Actonel 5 mg daily in the MERIT-OP Study.[1,3]*
- Actonel 150 mg Once-a-Month has an overall safety and tolerability profile similar to Actonel 5 mg daily.[1,3]
- Actonel is approved to reduce the incidence of vertebral fractures and a composite endpoint of nonvertebral osteoporosis-related fractures (wrist, clavicle, humerus, pelvis, leg, and hip).

*In a study of 1292 postmenopausal women >50 years of age with a lumbar spine (LS) BMD T-score <-2.5 OR a LS BMD T-score <-2.0 and at least one prevalent vertebral fracture, Actonel 150 mg Once-a-Month was shown to be non-inferior to Actonel 5 mg daily. The upper limit of the 95% two-sided confidence interval for the difference in mean percent change from baseline in LS BMD between the 5 mg daily group and the 150 mg Once-a-Month group was less than the pre-defined non-inferiority margin of 1.5% at Endpoint (upper limit 95% two-sided CI = 0.2744).

Actonel is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

1. Actonel package insert. Cincinnati, Ohio: Procter & Gamble Pharmaceuticals; April 2008.
2. Procter & Gamble Pharmaceuticals Price List, April 2008, Actonel 35 mg and Actonel 150 mg.
3. Delmas PD, McClung MR, Zanchetta JR, et al. Efficacy and safety of risedronate 150 mg once a month in the treatment of postmenopausal osteoporosis. *Bone.* 2008;42(1):36-42.

Please see provided Full Prescribing Information for Actonel.
Please see Selected Safety Information for Actonel on reverse.

150 mg
Actonel®
(risedronate sodium) tablets
Once-a-Month

Actonel is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

Selected Safety Information for Actonel® (risedronate sodium) tablets

Actonel is contraindicated in patients with hypocalcemia, known hypersensitivity to any component of this product, or inability to stand or sit upright for at least 30 minutes. Hypocalcemia and other disturbances of bone and mineral metabolism should be effectively treated before starting Actonel therapy. Actonel is not recommended for use in patients with severe renal impairment (creatinine clearance <30 mL/min).

Bisphosphonates, including Actonel, may cause upper gastrointestinal disorders such as dysphagia, esophagitis and esophageal or gastric ulcers. Actonel should be taken according to the dosing instructions to minimize the risk of these events. Patients should discontinue use if new or worsening symptoms occur.

There have been reports of severe and occasionally incapacitating bone, joint and/or muscle pain in patients taking bisphosphonates. Rare occurrences of osteonecrosis, primarily of the jaw (ONJ), have been reported in patients treated with bisphosphonates. Most cases were reported in cancer patients receiving intravenous bisphosphonates, but some have been in patients treated orally for osteoporosis. Most cases were reported in patients undergoing dental procedures such as tooth extraction.

Most common adverse reactions reported in >10% of patients treated with ACTONEL and with a higher frequency than placebo are: back pain, arthralgia, abdominal pain, and dyspepsia. Hypersensitivity reactions (angioedema, generalized rash, bullous skin reactions), and eye inflammation (iritis, uveitis) have been reported rarely.

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P&G Pharmaceuticals

sanofi aventis

150 mg Actonel® (risedronate sodium) tablets Once-a-Month