

# The Medical Letter®

## On Drugs and Therapeutics

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### IN BRIEF

#### Cancer Risk with Salmon Calcitonin

Two FDA advisory committees recently concluded that use of a nasal spray formulation of the peptide hormone salmon calcitonin for treatment of postmenopausal osteoporosis is associated with an increased risk of cancer. Salmon calcitonin is available as 2 nasal sprays (*Miacalcin*, *Fortical*) and an injectable formulation (*Miacalcin Injection*) for use in osteoporosis.<sup>1</sup>

The new cancer concern arose from the results of an unpublished meta-analysis that included 18 studies of *Miacalcin Nasal Spray* in which the risk of any cancer was 1.54 times greater (95% CI: 1.06, 2.23) in patients who used the drug compared to controls.<sup>2</sup>

An earlier 5-year trial in >1200 postmenopausal women with osteoporosis also found that use of calcitonin was associated with a small, but statistically significant, increase in the risk of any malignancy (OR 1.62, 95% CI: 1.00, 2.61).<sup>2</sup> New vertebral fractures occurred in 51 of 287 women (18%) receiving a 200 IU dose of calcitonin nasal spray once daily and in 70 of 270 women (26%) receiving placebo, a statistically significant difference.<sup>3</sup>

The advisory committees, meeting jointly, weighed the risk against the benefits of the drug and concluded that women should no longer use salmon calcitonin nasal spray for treatment of postmenopausal osteoporosis. The FDA now has to decide whether to approve their recommendations.

1. Drugs for postmenopausal osteoporosis. *Treat Guidel Med Lett* 2011; 9:67.
2. Novartis. FDA Joint Reproductive Health Drugs and Drug Safety and Risk Management Advisory Committee meeting on the benefit/risk of salmon calcitonin for the treatment of postmenopausal osteoporosis. Briefing book. Available at [www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM341781.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM341781.pdf). Accessed April 4, 2013.
3. CH Chesnut 3rd et al. A randomized trial of nasal spray salmon calcitonin in postmenopausal women with established osteoporosis: the prevent recurrence of osteoporotic fractures study. *PROOF Study Group. Am J Med* 2000; 109:267.

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