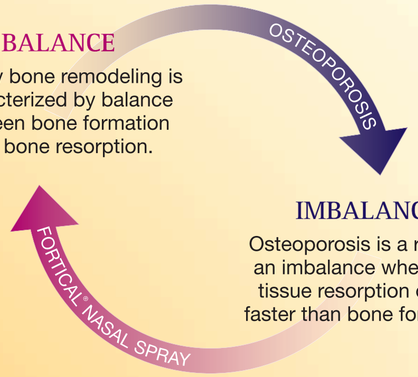
A novel calcitonin-salmon formulation designed for individualizing treatment options

- Manufactured by unique recombinant DNA technology[1]
- Essentially identical in action to endogenous calcitonin, but more potent[1]
- Does not contain benzalkonium chloride

Fortical® Nasal Spray helps restore the balance between bone formation and resorption[1]*



†A 5-year multicenter clinical trial (Prevent Recurrence of Osteoporotic Fractures [PROOF] study) to determine the long-term efficacy of calcitonin-salmon nasal spray in the prevention of new vertebral fractures in postmenopausal women with osteoporosis. 1,255 women were randomly assigned to receive calcitonin-salmon nasal spray (100, 200 or 400 IU), or placebo, with calcium and vitamin D daily. Vertebral fractures were assessed with lateral radiographs of the spine. The primary efficacy endpoint was risk of new vertebral fractures in the 200 IU calcitonin-salmon group compared with the placebo group. Study was performed with another commercially available calcitonin-salmon nasal spray.

‡A 2-year, double-blind, placebo-controlled, randomized, parallel-group clinical trial of 208 postmenopausal women with moderate osteoporosis, randomized to receive calcitonin-salmon nasal spray (50, 100 or 200 IU) or placebo, with calcium daily. Study was performed with another commercially available calcitonin-salmon nasal spray.

§Subanalysis of 81 postmenopausal women with low bone mass receiving 200 IU calcitonin-salmon nasal spray or placebo, with calcium daily, from a 2-year, double-blind, placebo-controlled, randomized, parallel-group clinical trial. Study was performed with another commercially available calcitonin-salmon nasal spray.

‖A 2-year prospective trial (Qualitative Evaluation of Salmon Calcitonin Therapy [QUEST] study) of 91 postmenopausal osteoporotic women using a unique noninvasive MRI technique to assess trabecular microarchitecture of the radius, hip, and os calcis in patients receiving 200 IU calcitonin-salmon nasal spray or placebo, with calcium daily. Study was performed with another commercially available calcitonin-salmon nasal spray.

*Although not completely elucidated, the mechanism of action depicted in this simplified graphic represents a complex continuous process. Calcitonin-salmon is intended to be used as long-term therapy.

References: 1. Fortical® calcitonin-salmon (rDNA origin) Nasal Spray product information. Upsher-Smith Laboratories, Inc. **2.** Chesnut CH, Silverman S, Andriano K, et al; PROOF Study Group. A randomized trial of nasal spray salmon calcitonin in postmenopausal women with established osteoporosis: the Prevent Recurrence of Osteoporotic Fractures Study. *Am J Med.* 2000;109:267-276. **3.** Overgaard K, Hansen MA, Jensen SB, Christiansen C. Effect of salcatonin given intranasally on bone mass and fracture rates in established osteoporosis: a dose-response study. *BMJ.* 1992;305:556-561. **4.** Overgaard K, Lindsay R, Christiansen C. Patient responsiveness to calcitonin salmon nasal spray: a subanalysis of a 2-year study. *Clin Ther.* 1995;17:680-685. **5.** Data on file, Upsher-Smith Laboratories, Inc. **6.** Chesnut CH, Majumdar S, Newitt DC, et al. Effects of salmon calcitonin on trabecular microarchitecture as determined by magnetic resonance imaging: results from QUEST study. *J Bone Miner Res.* 2005;20:1548-1561.

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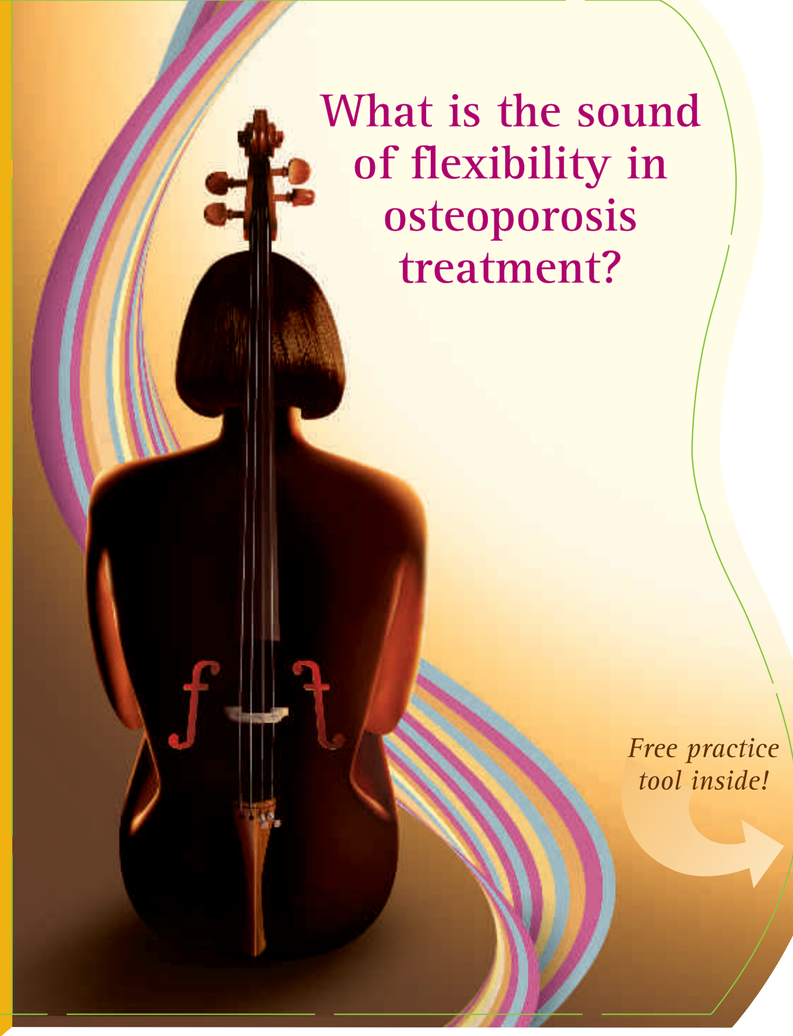


What is the sound of flexibility in osteoporosis treatment?

Free practice tool inside!

A flexible addition to give you more computer options

This USB hub is designed to add more flexibility to your computer by allowing you to extend the number of USB ports available to you.

Add a flexible option to your bone health ensemble

fortical® calcitonin-salmon (rDNA origin) Nasal Spray

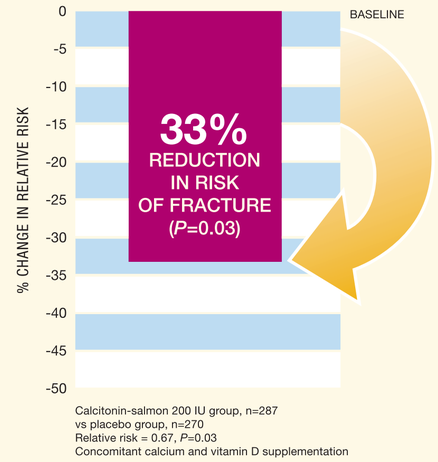
Harmonious with women's health.

IMPORTANT SAFETY INFORMATION

Indicated for the treatment of postmenopausal osteoporosis in women greater than 5 years postmenopause with low bone mass relative to healthy premenopausal women. Recommended in conjunction with adequate calcium and vitamin D intake. The most common adverse events were rhinitis, other nasal symptoms, back pain, arthralgia, epistaxis, and headache. Periodic nasal examinations are recommended; if nasal ulceration occurs, discontinue treatment until healed. Because calcitonin-salmon is a protein, the possibility of systemic allergic reaction exists. Please see accompanying important prescribing information.

Calcitonin-salmon has been shown to reduce the risk of vertebral fractures by one-third

REDUCTION IN RISK OF DEVELOPING A NEW FRACTURE VS PLACEBO DURING A 5 YEAR STUDY[†2]



Calcitonin-salmon 200 IU group, n=287
vs placebo group, n=270
Relative risk = 0.67, *P*=0.03
Concomitant calcium and vitamin D supplementation

Multiple studies demonstrate additional calcitonin-salmon efficacy

- Shown to increase vertebral bone mineral density (BMD) by an average of 3% (95% CI: 1.8% - 4.2%) from baseline[‡3]
- Shown to reduce the risk of bone loss by **81%** versus placebo[§4]
- Shown to rapidly decrease plasma markers of bone resorption as early as 1 month of use[5]
- Shown to preserve or improve trabecular microarchitecture[‖6]