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INNOVATIVE TREATMENT FOR OSTEOPOROSIS, FOSAVANCE™, INTEGRATES TWO ESSENTIAL ELEMENTS OF TREATMENT –MEDICATION AND VITAMIN D – IN A SINGLE ONCE-WEEKLY TABLET

More than 60 per cent of Canadians with osteoporosis are not getting enough vitamin D, without which calcium cannot be absorbed by bones

MONTREAL, Québec (March 28, 2006) – Women and men with osteoporosis now have an innovative treatment that, for the first time, can provide fracture prevention at both the hip and spine related to osteoporosis^{1,2,3}, with the assurance of Vitamin D dosed weekly. Now available in Canada, FOSAVANCE™ (alendronate sodium 70 mg/cholecalciferol 2800 IU [Vitamin D₃]) is the first and only therapy for the treatment of osteoporosis, which integrates, FOSAMAX® (alendronate sodium 70 mg) and Vitamin D₃ (cholecalciferol 2800 IU), in a single, once-weekly tablet, the same size as FOSAMAX® alone.

“This treatment represents an important advancement for people with osteoporosis, providing the same efficacy and tolerability of FOSAMAX®, together with Vitamin D₃*,” said Dr. Aliya Khan, Associate Clinical Professor of Medicine, Divisions of Endocrinology and Geriatrics at McMaster University and Director of the Calcium Disorders Clinic at St. Joseph’s Healthcare at McMaster. “Most patients know that calcium is important, but do not realize that Vitamin D is essential for calcium absorption and building strong, healthy bones to help prevent fractures. This effective option will help physicians to better manage their patient’s Vitamin D intake and bone health.”

Vitamin D[†] inadequacy and non-compliance are significant issues in Canada, especially among people with osteoporosis:

- A Canadian study indicates that by current definition of normal vitamin D health[†], a majority of adult Canadians have inadequate levels of Vitamin D.⁴
- Studies conducted in North America, Latin America, Europe, the Middle East, Asia and the Pacific Rim have shown that more than half of postmenopausal women with osteoporosis have inadequate levels of Vitamin D.^{5,6,7}

* Vitamin D₃, also known as cholecalciferol, is the natural human form of vitamin D.

† Inadequate vitamin D levels are defined as serum-25 hydroxyvitamin D (25(OH)D) levels less than 75 nmol/L (30 ng/ml).

- Another study found that 97 per cent of patients hospitalized with a fracture, such as a minor fall, had Vitamin D inadequacy.⁸
- IMS Health Canada data reveals that Vitamin D was prescribed at only 13 per cent of osteoporosis related visits in 2000.⁹
- Studies show that patients also frequently discontinue taking prescribed Vitamin D and calcium supplementation.^{10,11}

“All of the information we have about Vitamin D tells us that Canadians need to be more proactive in ensuring their Vitamin D levels are adequate. No matter how much calcium a person with osteoporosis may get, their bones will suffer the consequences if they do not include Vitamin D,” said Andrea Miller, Community and Family Practice dietitian, Women’s College campus of Sunnybrook and Women’s College Health Sciences Centre in Toronto. “FOSAVANCE™ ensures that people will get Vitamin D to improve calcium absorption and help protect themselves from osteoporosis-related fractures.”

According to Osteoporosis Canada’s 2002 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada the recommended daily dose of Vitamin D for men and women under the age of 50 is 400 IU and over the age of 50 is 800 IU.¹² FOSAVANCE™, with 2800 IU once weekly of Vitamin D₃, provides the assurance that patients are receiving a significant portion of the Canadian recommended intake of Vitamin D.

FOSAVANCE™ (ALENDRONATE SODIUM 70 MG/CHOLECALCIFEROL 2800 IU [VITAMIN D₃])

FOSAVANCE™ represents an innovative therapeutic option for patients with osteoporosis, building on the efficacy and tolerability of FOSAMAX® with the assurance of Vitamin D dosed weekly. FOSAVANCE™ is indicated for the treatment of osteoporosis in postmenopausal women and men to increase bone mineral density (BMD) and can prevent fractures, including those of the hip and spine. It contains a weekly dose of alendronate sodium 70 mg, the world’s leading osteoporosis treatment.

Alendronate sodium has demonstrated consistent and substantial reductions in hip^{13,14,15} and spine fractures^{16,17,18,19} in numerous studies, as well as substantial increases in bone mineral density (BMD),^{20,21,22} and reductions in bone turnover (a process where bone is constantly being resorbed and replaced).^{23, 24}

The long-term efficacy and tolerability profile of alendronate sodium has been demonstrated in a landmark study published in *The New England Journal of Medicine* entitled ‘Ten year experience with alendronate for osteoporosis treatment in postmenopausal women’. This study was conducted over 10 years of therapy – the longest clinical trial of any osteoporosis treatment.²⁵ FOSAMAX[®] has been prescribed to 12 million people with osteoporosis worldwide since it was first introduced.²⁶

FOSAVANCE[™], with 2800 IU once weekly of Vitamin D₃, provides the assurance that patients are receiving a significant portion of the Canadian recommended intake of Vitamin D. As demonstrated in a recent 717-patient clinical study, patients treated with alendronate sodium 70mg/cholecalciferol 2800 IU [Vitamin D₃] had significantly higher vitamin D₃ levels than those treated with alendronate alone, after only 15 weeks of therapy (p<0.001).²⁷

“The innovation of adding another essential treatment element, vitamin D₃, in the same tablet with FOSAMAX[®], which has been a gold standard in osteoporosis treatment to prevent fractures of the hip and spine for more than ten years, makes FOSAVANCE[™] an important advancement in the arsenal of osteoporosis care,” said Dr. François Bertrand, Executive Director of Medical Research. “The introduction of this innovative medication demonstrates Merck Frosst’s commitment to leadership and care in osteoporosis treatment and management.”

THE FACTS ABOUT VITAMIN D AND OSTEOPOROSIS

- The main source of Vitamin D is exposure to sunlight; however, many factors affect the amount of Vitamin D produced in the skin, including: season, geographic latitude, time of day, cloud cover, smog, clothing, sunscreen and skin pigmentation.
- As people age, their skin becomes less able to convert sunshine into Vitamin D and the kidney is less able to convert Vitamin D to its active form.^{28,29,30}
- Osteoporosis, a chronic condition that leads to bone loss and susceptibility to fractures, affects 1.4 million Canadians – approximately one in four women and at least one in eight men over the age of 50.³¹
- Research has shown that up to one in five women who suffers a hip fracture dies within one year.³²

ABOUT MERCK FROSST CANADA LTD.

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company. Merck Frosst discovers, develops and markets a broad range of innovative medicines to improve human health. Merck Frosst is one of the top 20 R&D investors in Canada, with an investment of \$117 million in 2004. The Company is committed to fostering partnerships to deliver the most valuable health outcomes for Canadian patients. More information about Merck Frosst is available at <http://www.merckfrosst.com>

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