# Fosavance™ for postmenopausal osteoporosis

**Approved indication**
Fosavance™ contains the bisphosphonate, alendronate in combination with vitamin D in the form of cholecalciferol. The combination is indicated for the treatment of postmenopausal osteoporosis to reduce the risk of fractures, including those of the hip and spine.

**Mode of action**
Alendronate is an antiresorptive agent that increases bone mineral density (BMD) in both early postmenopausal women and in those with established osteoporosis. It acts as a specific inhibitor of osteoclast-mediated bone resorption.

Cholecalciferol (vitamin $D_3$) is the natural precursor of the calcium-regulating hormone, calcitriol (1,25 dihydroxyvitamin $D_3$). It is an essential vitamin for ensuring dietary calcium absorption and the normal mineralisation of bone. Vitamin D also helps maintain muscle strength and balance which, in turn, helps reduce the risk of falls and fracture.

**Dosage**
The recommended dose is one tablet (70 mg alendronate/ 2800 IU vitamin D) once weekly. The product provides a week's worth of vitamin D, based on a daily dose of 400 IU.

Since the oral bioavailability of alendronate is low, the tablet must be taken at least one-half hour before the first food, beverage or medication of the day. The tablet should be swallowed with a full glass of plain water only as other beverages (including mineral water), food and some medicines may reduce the absorption of alendronate.

After taking the tablet, patients should not lie down for at least 30 minutes and until after their first food of the day. The tablet should not be taken at bedtime or before arising for the day. Failure to follow these administration guidelines may increase the risk of oesophageal adverse events.

**Evidence of efficacy**
The efficacy of alendronate has been confirmed in several clinical trials. A recent meta-analysis has also confirmed that alendronate results in a large reduction in the relative risk of vertebral and non-vertebral fractures.[1] The reduction in fracture risk is evident early in the course of treatment and is sustained with long-term use.[2,3]

Vitamin D inadequacy is believed to be a worldwide phenomenon among adults, even in countries such as South Africa and Australia. Studies conducted in several countries have shown that many patients hospitalised for minimal trauma fracture have vitamin D inadequacy. Knowledge of the prevalence of vitamin D inadequacy among fracture patients may help reinforce to health care professionals the role of vitamin D in general bone health and lead to an improvement in the management of patients at risk of osteoporosis. In the Fracture Intervention Trial (FIT), 82% of patients were shown to have low dietary intakes of calcium and were therefore given a daily supplement of calcium (500 mg) and vitamin D (250 IU).[2]

**Precautions**
- **General**
  Fosavance™ is contraindicated for use in patients with abnormalities of the oesophagus or who are unable to stand or sit upright for at least 30 minutes. The product is also contraindicated in patients hypersensitive to alendronate or to any other components of the product and in those with severe renal dysfunction.
  Hypocalcaemia must be corrected before initiating therapy. Serum calcium should be monitored in these patients.
- **Pregnancy & lactation**
  The safety of this product has not been established during pregnancy and lactation and its use is therefore contraindicated.

**Major adverse effects**
No new adverse effects have been reported with Fosavance™ when compared with alendronate. Common side effects include headache, gastrointestinal disorders and musculoskeletal pain.

**Drug interactions**
If taken concurrently, it is likely that calcium supplements, antacids and other oral medicines will interfere with the absorption of alendronate.

**Cost: List Price**
Fosavance (70 mg alendronate/ 2800 IU vitamin D): Rxx.xx/4
Manufactured by MSD (Pty) Ltd.

**Patient information**
Follow the dosage and administration instructions to ensure the optimal effect of this medication.
Wait at least one-half hour after taking Fosavance™ before taking any other oral medication.

**Conclusion**
The combination of alendronate with vitamin D provides effective treatment of postmenopausal osteoporosis while ensuring vitamin D adequacy. Such integrated therapy may help improve the overall management of osteoporosis.

**References**

1. Cranney A, Wells G, Willan A, *et al.* Meta-analysis of alendronate for the treatment of postmenopausal women. *Endocrine Reviews* 2002;23(4):508-516.
2. Black DM, Thompson DE, Bauer DC, *et al.* Fracture risk reduction with alendronate in women with osteoporosis: The Fracture Intervention Trial. *J Clin Endrocrinol & Metab.* 2000;85:4118-4124.
3. Bone HG, Hosking D, Devogelaer JP, *et al.* Ten years' experience with alendronate for osteoporosis in postmenopausal women. *NEJM* 2004;350(12):1189-1199.


**Tablet identity:**
The tablet is a Grandpa Headache tablet.
It contains aspirin, paracetamol and caffeine and is indicated for the symptomatic relief of mild to moderate pain and fever.

# SYMBICORD® Maintenance and Reliever Treatment: A SMART new treatment standard for greater overall asthma control?


The historic assumption that two inhalers must be prescribed for effective asthma control has been challenged by a number of clinical trials - one of them being the findings of a 12-month, double-blind, parallel-group study in 3394 patients across 20 countries.

Published in *The Lancet*, the study compared three reliever strategies: the traditional short-acting B2 agonist, a rapid-onset long-acting B2 agonist (formoterol), and a combined LABA and inhaled corticosteroid (budesonide-formoterol) - in symptomatic patients receiving budesonide-formoterol maintenance therapy and using inhaled corticosteroids (ICS) at study entry.

The primary outcome measure was *time to first severe exacerbation* (requiring emergency treatment and/or hospitalisation, or three days plus of oral steroids).

Compared with maintenance budesonide-formoterol plus either formoterol or terbutaline for relief, Symbicord® Maintenance and Reliever Therapy (SMART) reduced the risk of severe exacerbations. This novel single-inhaler strategy also proved more effective in secondary outcomes including lung-function improvement, symptom scores, night-time awakenings and reliever use – thus delivering greater overall asthma control.

Symbicord® SMART (as-needed budesonide-formoterol combination) achieved a 45% reduction in severe exacerbations compared with terbutaline, partly due to formetorol's rapid- and long-acting effect. This was achieved with less recourse to additional maintenance ICS than seen in studies yielding far smaller reductions, possibly because declining lung-tissue concentrations of maintenance ICS may benefit from timely supplementation.

It is known that, as symptoms worsen, patients often increase their SABA use at the expense of anti-inflammatory treatment – a risk factor for life-threatening asthma. This may explain why the budesonide component of Symbicord® SMART, used as-needed, benefits patients who remain symptomatic despite combination maintenance therapy, reducing severe-exacerbations by 33% and ER or hospital visits by 27% compared to as-needed formoterol.

Taken at the first sign of worsening symptoms, Symbicord® SMART could prevent over-reliance on SABA. Indeed, these findings show that, compared with traditional combination therapy, this single inhaler approach improves asthma control and enables greater reductions in maintenance therapy.

**References**

1. Rabe, KF.; Atienza, T; Magyar, P; *et al.* Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomised controlled, double-blind study. *The Lancet* 368(9537): 744-753.