

PART III: CONSUMER INFORMATION**FOSAVANCE® 70/2800**

(alendronate sodium/cholecalciferol)

Once Weekly Tablets**70 mg alendronate + 70 mcg cholecalciferol
(2800 IU vitamin D₃)****FOSAVANCE® 70/5600**

(alendronate sodium/cholecalciferol)

Once Weekly Tablets**70 mg alendronate + 140 mcg cholecalciferol
(5600 IU vitamin D₃)**

This leaflet is Part III of a three-part “Product Monograph” published when FOSAVANCE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FOSAVANCE®. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this insert carefully before starting FOSAVANCE® and every time your prescription is renewed.

ABOUT THIS MEDICATION**WHAT THE MEDICATION IS USED FOR:**

FOSAVANCE® is the brand name for a tablet that contains alendronate sodium and cholecalciferol (vitamin D₃) as the active ingredients. It is available **only on prescription** from your doctor. Alendronate sodium is a member of a class of non-hormonal drugs called bisphosphonates. Cholecalciferol is the natural form of vitamin D.

Your doctor has prescribed FOSAVANCE® because you have a disease known as osteoporosis. FOSAVANCE® is indicated for treatment of osteoporosis in post-menopausal women and in men.

Since it is not known how long FOSAVANCE® should be continued for osteoporosis, you should discuss the need to stay on this medication with your doctor regularly to determine if FOSAVANCE® is still right for you.

WHAT IT DOES:**How is normal bone maintained?**

Bone undergoes a normal process of rebuilding that occurs continuously throughout your skeleton. First, old bone is removed (resorbed), then new bone is laid down (formed). This balanced process of resorbing and forming bone keeps your skeleton healthy and strong.

What is osteoporosis and why should it be treated?

Osteoporosis is a thinning and weakening of the bones. It is common in women after menopause and may also occur in men. Osteoporosis often occurs in women several years after the menopause, which occurs when the ovaries stop producing the

female hormone, estrogen, or are removed (which may occur, for example, at the time of a hysterectomy). The earlier a woman reaches the menopause, the greater the risk of osteoporosis. Osteoporosis can also occur in men due to several causes, including aging and/or a low level of the male hormone, testosterone. In all instances, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. Therefore, maintaining bone mass and preventing further bone loss are important to keep your skeleton healthy. Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in fractures (broken bones). Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone. Fractures usually occur at the hip, spine, or wrist and can lead not only to pain, but also to considerable deformity and disability (such as stooped posture from curvature of the spine, and loss of mobility).

What should I know about vitamin D?

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. Winter sunlight in Canada is too weak to produce vitamin D. Even in the summer, clothing or sun block can prevent enough sunlight from getting through. In addition, as people age, their skin becomes less able to make vitamin D. Very few foods are natural sources of vitamin D. Some foods (for example, milk, select brands of orange juice and breakfast cereals) are fortified with vitamin D.

Too little vitamin D leads to inadequate calcium absorption and low phosphate – the minerals that make bones strong. Even if you are eating a diet rich in calcium or taking a calcium supplement, your body cannot absorb calcium properly unless you have enough vitamin D. Too little vitamin D may lead to bone loss and osteoporosis, and severe vitamin D deficiency may cause muscle weakness which can lead to falls, and greater risk of fracture. Vitamin D supplements reduce these risks and their consequences.

FOSAVANCE® alone should not be used to treat vitamin D deficiency.

How can FOSAVANCE® treat your osteoporosis?

Your doctor has prescribed FOSAVANCE® to treat your osteoporosis. The alendronate sodium component of FOSAVANCE® not only prevents the loss of bone but actually helps to rebuild bone you may have lost and increases your bone mass. This makes bone stronger and less likely to fracture. Thus, FOSAVANCE® reverses the progression of osteoporosis.

If you are over the age of 70, home bound, or suffer from a long-term illness, you may need to receive vitamin D in addition to that provided in FOSAVANCE®. Because winter sunlight in Canada is too weak to produce vitamin D, most people living in Canada may also need additional vitamin D.

FOSAVANCE® does not contain calcium. Your doctor may recommend calcium supplements.

In addition, your doctor may recommend one or more of the following lifestyle changes:

Stop smoking. Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture.

Exercise. Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise program.

Eat a balanced diet. Your doctor can advise you whether to modify your diet or to take any dietary supplements.

Reduce the use of alcohol.

WHEN IT SHOULD NOT BE USED:

Do NOT take FOSAVANCE® if you:

- Have certain disorders of the esophagus (the tube that connects your mouth with your stomach).
- Are unable to stand or sit upright for at least 30 minutes.
- Are allergic to any of its ingredients.
- Have low blood calcium.
- Have SEVERE kidney disease. If you have any doubts if this applies to you, speak to your doctor.

WHAT THE MEDICINAL INGREDIENTS ARE:

Each tablet of FOSAVANCE® (70 mg/2800 IU) contains 70 mg of alendronate and 70 mcg of cholecalciferol (2800 IU of vitamin D₃).

Each tablet of FOSAVANCE® (70 mg/5600 IU) contains 70 mg of alendronate and 140 mcg of cholecalciferol (5600 IU of vitamin D₃).

WHAT THE NONMEDICINAL INGREDIENTS ARE:

butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, gelatin, lactose anhydrous, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, modified food starch (corn), sodium aluminum silicate and sucrose.

FOSAVANCE® tablets are gluten free.

WHAT DOSAGE FORMS IT COMES IN:

FOSAVANCE® (70 mg/2800 IU) is available as a white to off-white, modified capsule-shaped tablet, with code 710 on one side.

FOSAVANCE® (70 mg/5600 IU) is available as a white to off-white, modified rectangle-shaped tablet, with code 270 on one side.

- have cancer, gum disease, poor oral hygiene, or diabetes.
- get chemotherapy, or radiotherapy.
- take corticosteroids, or immunosuppressive drugs.
- take angiogenesis inhibitors; they are drugs that slow down the growth of new blood vessels and are used mostly to treat cancer (e.g. bevacizumab).
- are or have been a smoker.
- are a heavy alcohol user.

If any of the above apply to you, have a dental check-up before starting FOSAVANCE®.

- have or have had any medical problems including known kidney disease.
- have or have had any dental problems.
- have any allergies.
- have any swallowing or digestive problems.

Your doctor may check if you:

- smoke.
- have or have had teeth and/or gum disease.
- have dentures that do not fit well.
- have other relevant medical conditions at the same time, such as; low red blood cell count (called anemia) or if your blood cannot form clots in the normal way.

Digestive problems

Some patients may experience digestive problems while taking FOSAVANCE®, which may be severe, including irritation or ulceration of the esophagus (the tube that connects your mouth with your stomach), which can cause chest pain, heartburn or difficulty or pain upon swallowing. These reactions may occur especially if patients do not drink the recommended amount of water with FOSAVANCE® and/or if they lie down in less than 30 minutes or before their first food of the day.

Talk to your doctor:

- if you have ear pain and/or discharge from the ear while taking FOSAVANCE® as these could be signs of bone damage in the ear.

Use in pregnancy and breast-feeding

Do not take FOSAVANCE® if you are pregnant or breast-feeding.

Use in children

FOSAVANCE® is not indicated for anyone under 18 years of age and should not be given to them.

Use in elderly

FOSAVANCE® works equally well in, and is equally well tolerated by, patients older and younger than 65 years of age.

There have been side effects reported with FOSAVANCE® that may affect your ability to drive or operate machinery. Individual responses to FOSAVANCE® may vary.

WARNINGS AND PRECAUTIONS

BEFORE you use FOSAVANCE® talk to your doctor or pharmacist if you:

FOSAVANCE® (alendronate sodium/cholecalciferol)

INTERACTIONS WITH THIS MEDICATION

You should always tell your doctor about all drugs you are taking or plan to take, including those obtained without a prescription, vitamins, and herbal products.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of alendronate if taken at the same time of the day. You must wait at least one-half hour after taking FOSAVANCE® before taking any other oral medication.

It is likely that certain medicines or food additives may prevent the vitamin D in FOSAVANCE® from getting into your body, including artificial fat substitutes, mineral oils, orlistat and the cholesterol-lowering medicines, cholestyramine and colestipol. Medicines for seizures (convulsions), cimetidine and thiazides (diuretic) may decrease the effectiveness of vitamin D.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

These are the important things you must do to help make sure you will benefit from FOSAVANCE®:

1. **Choose the day of the week that best fits your schedule. Every week, take one FOSAVANCE® tablet on your chosen day.**

2. **After getting up for the day and before taking your first food, beverage, or other medication, swallow your FOSAVANCE® tablet with a full glass (200-250 mL) of plain water only.**

Do **NOT** take FOSAVANCE® with:

- Mineral water
- Coffee or tea
- Juice

Although it has not been tested, because of high mineral content, “hard water” may decrease absorption of FOSAVANCE®. If your normal drinking water is classified as “hard water”, you should consider taking this medication with distilled water (i.e., not mineral water).

Do **NOT** chew or suck on a tablet of FOSAVANCE®.

3. **After swallowing your FOSAVANCE® tablet, do not lie down — stay fully upright (sitting, standing or walking) for at least 30 minutes and do not lie down until after your first food of the day.**

4. **Do NOT take FOSAVANCE® at bedtime or before getting up for the day.**

The above actions will help the FOSAVANCE® tablet reach your stomach quickly and help reduce the potential for irritation of your esophagus (the tube that connects your mouth with your stomach).

5. **After swallowing your FOSAVANCE® tablet, wait at least 30 minutes before taking your first food, beverage, or other**

medication of the day, including antacids, calcium supplements and vitamins. FOSAVANCE® is effective only if taken when your stomach is empty.

6. **If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAVANCE® immediately and call your doctor.**

7. It is important that you continue taking FOSAVANCE® for as long as your doctor prescribes it. FOSAVANCE® can treat your osteoporosis only if you continue to take it.

It is important to take FOSAVANCE® over the long-term to continue to help rebuild bone you may have lost. It is, therefore, important to follow your doctor's instructions for taking FOSAVANCE® without skipping doses or varying from your prescribed treatment schedule. It is also important to continue to follow your doctor's advice on lifestyle changes.

OVERDOSE:

If you take too many tablets, drink a full glass of milk and contact your doctor immediately. Do not induce vomiting. Do not lie down.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

MISSED DOSE:

If you miss a dose, just take one FOSAVANCE® tablet on the morning after you remember. *Do NOT take two tablets on the same day.* Return to taking one tablet once a week, as originally scheduled on your chosen day.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

FOSAVANCE® may have unintended or undesirable effects.

- digestive problems such as nausea, vomiting, diarrhea or constipation.
- disorders of your esophagus (the tube that connects your mouth with your stomach) including irritation which can cause chest pain, heartburn or difficulty or pain upon swallowing. Esophageal reactions may worsen if patients continue to take FOSAVANCE® after developing symptoms suggesting irritation of the esophagus.

If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAVANCE® immediately and call your doctor.

- bone, muscle and/or joint pain which is rarely severe.
- joint swelling or swelling in their hands or legs.
- transient flu-like symptoms (rarely with fever).

- rash that may be made worse by sunlight, hair loss.
- Allergic reactions such as hives or, rarely, swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing or swallowing, may occur.
- dizziness, vertigo (spinning sensation) or a changed sense of taste.
- symptoms of low blood calcium (for example, numbness or tingling around the mouth or in the hands or feet; muscle spasms in the face, hands, or feet).
- mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.

If any of these affects you severely, tell your doctor or your pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptoms / effects	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Uncommon			
Allergic reactions such as: - hives - swelling of the face, lips, tongue and/or throat - difficulty in breathing or swallowing			✓
Severe bone, joint, and/or muscle pain		✓	
New or unusual pain in the hip or thigh		✓	
Esophageal ulcers causing: - chest pain - heartburn - difficulty or pain upon swallowing			✓
Stomach or other peptic ulcers occasionally associated with black and/or bloody stools			✓
Jaw problems associated with delayed healing and infection, often following tooth extraction			✓
Eye inflammation associated with eye pain; eye redness; sensitivity to light, decreased vision			✓
Severe skin reactions			✓
Symptoms of low blood calcium: – numbness or tingling around the mouth or in the hands or feet – muscle spasms in the face, hands, or feet			✓
Rare			
Persistent ear pain		✓	

This is not a complete list of side effects. For any unexpected effects while taking FOSAVANCE[®], contact your doctor or pharmacist.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

***NOTE:** Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

HOW TO STORE IT

Should be stored at 25°C but can be kept between 15°C and 30°C. Protect from moisture and light. Store tablets in the original blister package until time of use.

Do not use this medicine after the month and year written after EXP (expiry date) on the container.

Remember to keep FOSAVANCE® and all medications safely away from children.

MORE INFORMATION

If you want more information about FOSAVANCE®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website or Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

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