

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FOSAVANCE®

alendronate sodium / cholecalciferol tablets

Read this carefully before you start taking **FOSAVANCE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FOSAVANCE**.

What is FOSAVANCE used for?

FOSAVANCE is used in adults:

- to treat osteoporosis in men and postmenopausal women. Osteoporosis is a thinning and weakening of the bones. FOSAVANCE helps to rebuild bone and makes bone less likely to fracture.
- that are at an increased risk of vitamin D insufficiency.

FOSAVANCE is not for use in children under 18 years of age.

How does FOSAVANCE work?

FOSAVANCE contains two medicinal ingredients; one called alendronate sodium and another called cholecalciferol (vitamin D₃). Cholecalciferol is the natural form of vitamin D. Alendronate sodium belongs to a class of non-hormonal drugs called bisphosphonates. The bisphosphonates are similar to a molecule naturally made in your body that will break down bone tissue. Alendronate binds to the receptors in your body to prevent the bone from breaking down. This process also helps rebuild bone.

What are the ingredients in FOSAVANCE?

Medicinal ingredients: alendronate sodium and cholecalciferol.

Non-medicinal ingredients: 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 comes in the following dosage forms:

Tablet:

- 70 mg alendronate sodium and 70 mcg (2800 IU) cholecalciferol.
- 70 mg alendronate sodium and 140 mcg (5600 IU) cholecalciferol.

Do not use 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 alendronate sodium, cholecalciferol or any other ingredients in FOSAVANCE. If you are not sure about this, talk to your healthcare professional before taking FOSAVANCE.
- Have low blood calcium.
- Have SEVERE kidney disease. If you have any doubts if this applies to you, speak to your healthcare professional.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FOSAVANCE. Talk about any health conditions or problems you may have, including if you:

- have low blood calcium or a condition that affects your ability to absorb minerals (i.e. Vitamin D deficiency). This condition must be treated before you begin treatment with FOSAVANCE. Your healthcare professional will monitor your condition during your treatment. You should consume a sufficient amount of calcium and Vitamin D if you are already receiving glucocorticoids medicines. Speak to your healthcare professional if you experience muscle spasms or nerve problems (i.e. abnormal tingling or prickling sensations).
- have digestive problems. These may include difficulty swallowing, esophagus diseases, ulcers, inflammation of the first part of the small intestines, and inflammation of the lining of the stomach.
- may be at risk of developing osteonecrosis (bone damage in the jaw). Speak to your healthcare professional if you have a planned dental extraction. Your healthcare professional may request a dental check-up before starting FOSAVANCE. You may also be at risk of causing bone damage to your jaw if you:
 - o have cancer
 - o have or had poor dental health, gum or teeth disease
 - o have poor oral hygiene, dentures that do not fit well.
 - o have anemia (low red blood cell count)
 - o have infection
 - o have a blood disorder where your blood cannot form clots in the normal way
 - o have diabetes (high blood sugar).
 - o get chemotherapy, or radiotherapy.
 - o take corticosteroids, or immunosuppressive drugs.
 - o 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).
 - o are or have been a smoker.
 - o are a heavy alcohol user.
- have or have had any medical problems including known kidney disease.
- have any allergies.

Other warnings you should know about:

High calcium levels

Taking FOSAVANCE may worsen conditions such as hypercalcemia (high levels of calcium in blood) and/or hypercalciuria (high levels of calcium in urine). This happens when you have a disease that is associated with your body overproduces calcium (e.g., leukemia, lymphoma, sarcoidosis).

Gastrointestinal Problems

Taking FOSAVANCE incorrectly may cause you to experience problems with your esophagus. Stop taking FOSAVANCE and speak to your healthcare professional if you experience difficulty or pain upon swallowing, chest/breastbone pain or new or worsening heartburn. To avoid problems with your esophagus and allow the drug to reach the stomach, consider the following instructions:

- swallow each tablet of FOSAVANCE with a full glass of water.
- do NOT cut, chew, crush or suck the tablet.
- do NOT lie down for at least 30 minutes and until your first meal of the day.
- do NOT take FOSAVANCE at bedtime or before starting your day.

Muscle and skeletal problems

Drugs such as FOSAVANCE may cause serious bone, joint or muscle pain. You may experience relief from these symptoms after you end your treatment. Long term treatment with FOSAVANCE may cause stress fractures (repetitive trauma) or low energy fractures (falls from standing). If you develop new or unusual pain in the hip, thigh or any other bone, contact your healthcare professional. Your healthcare professional will:

- evaluate your condition if they suspect you have developed a fracture.
- examine the cause of the stress fracture and provide appropriate care.
- pause your treatment depending on your condition.

Eye problems

Drugs such as FOSAVANCE may cause vision problems. Different parts of your eye may experience inflammation or you may develop an eye infection. Your healthcare professional may end your treatment if they identify symptoms of inflammation.

Bone damage in ear

Treatment with FOSAVANCE may cause bone damage in your ear. Talk to your healthcare professional if you have ear pain and/or discharge from the ear while taking FOSAVANCE.

Use in pregnancy and breast-feeding

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

Lifestyle changes

Consult with your healthcare professional about lifestyle changes when taking FOSAVANCE. These may include changes to your diet, use of dietary supplements, exercising and stop smoking.

Driving and using machines

Before you do tasks that may require special attention, wait until you know how you respond to FOSAVANCE. There have been side effects reported with FOSAVANCE that may affect your ability to drive or operate machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FOSAVANCE:

- Calcium supplements, antacids, and other oral medications will interfere with the absorption of FOSAVANCE if they are taken at the same time. You must wait at least half an hour after taking FOSAVANCE before taking any other oral medication.
- Intravenous ranitidine
- herbal products, food and beverages other than plain water may impact your ability to absorb FOSAVANCE. Wait at least half an hour after taking FOSAVANCE before you take any herbal products, food or beverages.
- 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.

How to take FOSAVANCE:

- Always take FOSAVANCE exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- It is important that you continue taking FOSAVANCE for as long as your healthcare professional prescribes it.
- Your healthcare professional may ask you to take calcium and vitamin D while you are on FOSAVANCE therapy.

Usual dose:

Take one FOSAVANCE tablet once a week.

Follow these instructions carefully:

1. Choose the day of the week that best fits your schedule. Every week, take one tablet of FOSAVANCE 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 only with plain water (200 to 250 mL). **Do NOT cut, chew, crush or suck on the tablet.** To make sure FOSAVANCE is absorbed by your body, do

NOT take FOSAVANCE with:

- mineral water
- coffee or tea
- juice

If your normal drinking water is classified as “hard water”, you should consider taking this medication with distilled water (i.e., not mineral water).

3. After taking your FOSAVANCE, 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. This will help FOSAVANCE:

- reach your stomach quickly and;
- reduce the potential for irritation of your esophagus (the tube that connects your mouth with your stomach).

5. After taking your FOSAVANCE, wait at least 30 minutes before taking your first food, beverage, or other medication of the day. This includes 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 healthcare professional.

Overdose:

If you take too much FOSAVANCE, drink a full glass of milk and contact your healthcare professional immediately. Do not make yourself vomit. Do not lie down.

If you think you, or a person you are caring for, have taken too much FOSAVANCE, contact a healthcare professional, 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 dose of FOSAVANCE on the morning after you remember. Do NOT take two doses on the same day. Return to taking one dose once a week, as originally scheduled on your chosen day.

What are possible side effects from using FOSAVANCE?

These are not all the possible side effects you may have when taking FOSAVANCE. If you experience any side effects not listed here, tell your healthcare professional.

- digestive problems
 - Acid reflux
 - Bloated feeling in stomach
 - Constipation
 - Diarrhea
 - Excessive gas

- Nausea
- Stomach pain
- Vomiting
- dizziness, spinning sensation or a changed sense of taste.
- flu-like symptoms (rarely with fever) and/or generally feeling unwell.
- joint swelling or swelling in your hands or legs.
- lack or loss of strength.
- mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.
- muscle cramps and/or aches
- skin problems
 - Rash that may be made worse by sunlight
 - Hair loss
 - Itchy skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	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 inflammation or ulcers causing: - chest pain - heartburn - difficulty or pain upon swallowing			√
Stomach inflammation, 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			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Eye inflammation associated with eye pain; eye redness; sensitivity to light, decreased vision			√
Stevens-Johnson syndrome and/or toxic epidermal necrolysis (Severe skin reactions): redness, blistering and/or peeling of large areas of the skin			√
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		√	
UNKNOWN			
New or unusual pain in locations other than the thigh bone		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store at room temperature (15°C – 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.

Keep out of reach and sight of children.

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 Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Organon Canada website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last Revised August 03, 2023

® N.V. Organon. Used under license.

© 2023 Organon Canada Inc. All rights reserved.