

PART III: CONSUMER INFORMATION



alendronate sodium tablets

70 mg alendronate once weekly dosage

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

Please read this insert carefully before starting FOSAMAX[®] once weekly and every time your prescription is renewed.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

FOSAMAX[®] is the brand name for the substance alendronate sodium available **only on prescription** from your physician. Alendronate sodium is a member of a class of non-hormonal drugs called bisphosphonates.

Your physician has prescribed FOSAMAX[®] because you have a disease known as osteoporosis. FOSAMAX[®] helps to rebuild bone. This will help prevent you from developing fractures.

Since it is not known how long FOSAMAX[®] should be continued for osteoporosis, you should discuss the need to stay on this medication with your doctor regularly to determine if FOSAMAX[®] 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 or prevented?

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).

How can osteoporosis be treated?

Your physician has prescribed FOSAMAX[®] to treat your osteoporosis. FOSAMAX[®] not only prevents the loss of bone but actually helps to rebuild bone you may have lost and makes bone less likely to fracture. Thus, FOSAMAX[®] reverses the progression of osteoporosis.

In addition, your physician 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 physician before you begin any exercise program.

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

WHEN IT SHOULD NOT BE USED:

Do NOT take FOSAMAX[®] 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.
- Have difficulty swallowing liquids. You should not take FOSAMAX[®] oral solution.
- 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 physician.

WHAT THE MEDICINAL INGREDIENT IS:

Each 70 mg tablet of FOSAMAX[®] contains alendronate sodium.

WHAT THE NONMEDICINAL INGREDIENTS ARE:

Anhydrous lactose, croscarmellose sodium, magnesium stearate and microcrystalline cellulose.

WHAT DOSAGE FORMS IT COMES IN:

Tablet 70 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use FOSAMAX[®] talk to your doctor or pharmacist if you:

- 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 FOSAMAX[®].

- 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.

You should always tell your physician about all drugs you are taking or plan to take, including those obtained without a prescription.

Talk to your doctor:

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

Use in pregnancy and breast-feeding

Do not take FOSAMAX[®] if you are pregnant or breast-feeding.

Use in children

FOSAMAX[®] is not indicated for use in children under 18 years of age.

Use in elderly

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

Driving and using machines: There have been side effects reported with FOSAMAX[®] that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX[®] may vary.

INTERACTIONS WITH THIS MEDICATION

Calcium supplements, antacids, and other oral medications will interfere with the absorption of FOSAMAX[®] if they are taken at the same time. You must wait at least one-half hour after taking FOSAMAX[®] before taking any other oral medication.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

Your doctor has prescribed FOSAMAX[®] once weekly tablets.

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

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

2. After getting up for the day and before taking your first food, beverage, or other medication, take your FOSAMAX[®] with plain water only as follows:

- Swallow one tablet with a full glass (200 to 250 mL) of plain water.

Do **NOT** take FOSAMAX[®] with:

- mineral water
- coffee or tea
- juice

Although it has not been tested, because of high mineral content, “hard water” may decrease absorption of FOSAMAX[®]. 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 FOSAMAX[®].

3. After taking your FOSAMAX[®], 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 FOSAMAX[®] at bedtime or before getting up for the day.

The above actions will help FOSAMAX[®] 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 taking your FOSAMAX[®], wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. FOSAMAX[®] 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 FOSAMAX[®] immediately and call your doctor.

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

Calcium and vitamin D are also important for strong bones. Your doctor may ask you to take calcium and vitamin D while you are on FOSAMAX[®] therapy.

It is important to take FOSAMAX[®] over the long-term to continue to help rebuild bone you may have lost. It is, therefore, important

to follow your physician's instructions for taking FOSAMAX® without skipping doses or varying from your prescribed treatment schedule. It is also important to continue to follow your physician's advice on lifestyle changes.

OVERDOSE:

If you take too many doses, drink a full glass of milk and contact your physician 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 dose of FOSAMAX® 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.

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

FOSAMAX® 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. These reactions may occur especially if patients do not drink the recommended amount of water with FOSAMAX® and/or if they lie down in less than 30 minutes or before their first food of the day. Esophageal reactions may worsen if patients continue to take FOSAMAX® after developing symptoms suggesting irritation of the esophagus.
- bone, muscle and/or joint pain.
- 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.
- 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 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 FOSAMAX®, 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

Store at room temperature (15°C–30°C).

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

Remember to keep FOSAMAX[®] and all medications safely away from children.

MORE INFORMATION

If you want more information about FOSAMAX[®]:

- 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.

This leaflet was prepared by Organon Canada Inc.

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