

IMPORTANT: PLEASE READ

CONSUMER INFORMATION

 **FOSAMAX[®]**

**alendronate sodium tablets
40 mg alendronate daily 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[®] 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 Paget's disease of bone.

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 Paget's disease of bone?

In Paget's disease, bone resorption and formation are abnormally increased resulting in weakened bone. This may lead to pain, deformity, and/or fracture.

How can Paget's disease of bone be treated?

Your physician has prescribed FOSAMAX[®] to treat this disease. FOSAMAX[®] slows down bone resorption, which allows the bone-forming cells time to rebuild normal bone.

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.
- 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 40 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:

FOSAMAX[®] is available as a white, triangular-shaped 40 mg tablet.

WARNINGS AND PRECAUTIONS

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

- If you have cancer, gum disease, poor oral hygiene, or diabetes. If you are receiving chemotherapy, radiotherapy, corticosteroids, or immunosuppressive drugs. If you are or have been a smoker, or are a heavy alcohol user. If you have any of these conditions you should consider having a dental examination before starting FOSAMAX[®].
- About any medical problems you have or have had, including known kidney disease.
- About any dental problems you have or have had.
- About any allergies.
- If you have any swallowing or digestive problems.

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

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.

Can I drive or operate machinery while using FOSAMAX®?

There have been side effects reported with FOSAMAX® that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX® may vary (See SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

INTERACTIONS WITH THIS MEDICATION

The use of acetylsalicylic acid (ASA) with 40 mg of FOSAMAX® may increase the chance of stomach upset. You should speak to your physician if you take ASA.

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:

How should I take FOSAMAX®?

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

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

- Not mineral water
- Not coffee or tea
- Not 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®.

2. After swallowing your FOSAMAX® 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.

3. Do not take FOSAMAX® at bedtime or before getting up for the day.

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

4. After swallowing your FOSAMAX® tablet, 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.

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

6. Take one FOSAMAX® tablet once a day, every day.

7. It is important that you continue taking FOSAMAX® for as long as your doctor prescribes 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.

Overdose:

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

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Missed dose:

Take FOSAMAX® once daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule of one tablet once a day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most patients do not have side effects from FOSAMAX®, however, as with any medicine, FOSAMAX® may have unintended or undesirable effects. Side effects usually have been mild. Some patients may experience digestive disturbances such as nausea, vomiting or black and/or bloody stools. Some digestive disturbances 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 a full glass 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.

Some patients may experience bone, muscle and/or joint pain which is rarely severe. Patients who develop severe bone, joint, and/or muscle pain should contact their physician. Most patients experienced relief after stopping the drug. Rarely, patients may also experience joint swelling or swelling in their hands or legs. Transient flu-like symptoms (rarely with fever), typically at the start of treatment, have occurred. In rare cases, patients taking FOSAMAX® may get itching or eye pain, or a rash that may be made worse by sunlight. Hair loss has been reported. Rarely, severe skin reactions may occur. 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. Patients may experience dizziness, vertigo (spinning sensation) or a changed sense of taste. Rarely, symptoms of low blood calcium may occur (for example, numbness or tingling around the mouth or in the hands or feet; muscle spasms in the face, hands, or feet). Rarely, stomach or other peptic ulcers (some severe) have occurred. Mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.

Rarely, patients have had jaw problems associated with delayed healing and infection, often following tooth extraction.

Rarely, patients have experienced fracture in a specific part of the thigh bone. If you develop new or unusual pain in the hip or thigh, contact your doctor.

Anytime you have a medical problem you think may be from taking FOSAMAX®, even if it is not listed above, talk to your doctor.

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			√
	Bone, joint, and/or muscle pain		√	
	New or unusual pain in the hip or thigh		√	
	Digestive disturbances causing: - chest pain - heartburn - difficulty or pain upon swallowing - black and/or bloody stools			√
	Esophageal, stomach or other peptic ulcers			√
	Jaw problems associated with delayed healing and infection, often following tooth extraction			√
	Severe eye pain			√
	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			√

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

HOW TO STORE IT

Store FOSAMAX® 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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345
By toll-free fax: 1-866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

or Merck Frosst Canada Ltd.:

By toll-free telephone: 1-800-567-2594
By toll-free fax: 1-877-428-8675

By regular mail:
Merck Frosst Canada Ltd.
P.O. Box 1005
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program or Merck Frosst Canada Ltd. do not provide medical advice.

MORE INFORMATION

How can I learn more about FOSAMAX[®] and Paget's disease of bone?

You may obtain further information from your physician or pharmacist, who has more detailed information about FOSAMAX[®] and Paget's disease of bone.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merckfrosst.com>

or by contacting the sponsor, Merck Frosst Canada Ltd., at:

1-800-567-2594

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