

## **PART III: CONSUMER INFORMATION**

**Pr ALENDRONATE - 70**  
**Alendronate Sodium Tablets**  
**Pro Doc Standard**  
**70 mg once weekly dosage**

### **OSTEOPOROSIS**

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

**Please read this insert carefully before starting ALENDRONATE once weekly and every time your prescription is renewed.**

### **ABOUT THIS MEDICATION**

What the medication is used for:

ALENDRONATE is the product 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 ALENDRONATE because you have a disease known as osteoporosis. ALENDRONATE helps to rebuild bone. This will help prevent you from developing fractures.

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

Alendronate sodium

What the non-medicinal ingredients are:

Magnesium stearate, mannitol and microcrystalline cellulose.

What dosage forms it comes in:

Tablets, 70 mg

**WARNINGS AND PRECAUTIONS**

**Before you use ALENDRONATE 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 ALENDRONATE.
- 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 ALENDRONATE if you are pregnant or breast-feeding.

**Use in children**

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

**Use in elderly**

ALENDRONATE 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 ALENDRONATE?**

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

**INTERACTIONS WITH THIS MEDICATION**

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

**PROPER USE OF THIS MEDICATION**

Usual dose:

**How should I take ALENDRONATE once weekly?**

Your doctor has prescribed ALENDRONATE tablets once weekly.

These are the important things you must do to help make sure you will benefit from ALENDRONATE.

1. **Choose the day of the week that best fits your schedule. Every week, take one ALENDRONATE tablet on your chosen day.**
2. **After getting up for the day and before taking your first food, beverage, or other medication, take your ALENDRONATE with plain water only as follows:**

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

Do **not** take ALENDRONATE tablet with:

- mineral water
- coffee or tea
- juice

3. Although it has not been tested, because of high mineral content, “hard water” may decrease absorption of ALENDRONATE. 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 ALENDRONATE.**
4. **After taking your ALENDRONATE 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.**
5. **Do not take ALENDRONATE at bedtime or before getting up for the day.**

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

6. **After taking ALENDRONATE tablet, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. ALENDRONATE is effective only if taken when your stomach is empty.**
7. **If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking ALENDRONATE immediately and call your doctor.**
8. If you miss a dose, just take one dose of ALENDRONATE tablet 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.
9. It is important that you continue taking ALENDRONATE for as long as your doctor prescribes it. ALENDRONATE 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 ALENDRONATE therapy.

**IMPORTANT: PLEASE READ**

**Why is it important to continue to take ALENDRONATE?**

It is important to take ALENDRONATE 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 ALENDRONATE 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 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:

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

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Most patients do not have side effects from ALENDRONATE; however, as with any medicine, ALENDRONATE 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 the recommended amount of water with ALENDRONATE and/or if they lie down in less than 30 minutes **or** before their first food of the day. Esophageal reactions may worsen if you continue to take ALENDRONATE 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 ALENDRONATE 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 ALENDRONATE, even if it is not listed above, talk to your doctor.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
<b>Symptoms / effects</b>		<b>Talk with your doctor or pharmacist</b>		<b>Stop taking drug and call your doctor or pharmacist</b>
		<b>Only if severe</b>	<b>In all cases</b>	
<b>Uncommon</b>	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			√
	Eye inflammation associated with eye pain; eye redness; sensitivity to light, decreased vision			√

**IMPORTANT: PLEASE READ**

	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 ALENDRONATE, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store ALENDRONATE at room temperature 15°C – 30°C (59°F - 86°F).

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

**Remember to keep ALENDRONATE and all medications safely away from children.**

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701 E  
Ottawa, ON KIA OK9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

**How can I learn more about ALENDRONATE and osteoporosis?**

You may obtain further information from your physician or pharmacist who has more detailed information about ALENDRONATE and osteoporosis.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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