

## PART III: CONSUMER INFORMATION

### **PrSandoz Alendronate Alendronate Sodium Tablets 10 mg alendronate daily dosage**

This leaflet is part III of a three-part "Product Monograph" published when Sandoz 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 Sandoz Alendronate. Contact your doctor or pharmacist if you have any questions about the drug.

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

#### **ABOUT THIS MEDICATION**

##### What the medication is used for:

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

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

Each Sandoz Alendronate Tablets 10 mg contains alendronate sodium.

##### What the nonmedicinal ingredients are:

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

##### What dosage forms it comes in:

Sandoz Alendronate 10 mg, a white to off-white, oval biconvex uncoated tablet with inscription '10' on one side and plain on the other side. Available in blister packages of 28 tablets.

#### **WARNINGS AND PRECAUTIONS**

##### **Before you use Sandoz Alendronate 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 inhibitor; 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 Sandoz Alendronate .

- 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.

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 Sandoz Alendronate as these could be signs of bone damage in the ear.

#### Use in pregnancy and breast-feeding

Do not take Sandoz Alendronate if you are pregnant or breast-feeding.

#### Use in children

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

#### Use in elderly

Sandoz 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 Sandoz Alendronate ?

There have been side effects reported with alendronate sodium that may affect your ability to drive or operate machinery. Individual responses to Sandoz 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 sodium if they are taken at the same time. You must wait at least one-half hour after taking Sandoz Alendronate before taking any other oral medication.

### PROPER USE OF THIS MEDICATION

#### Usual dose:

#### How should I take Sandoz Alendronate ?

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

#### 1. After getting up for the day and before taking your first food, beverage, or other medication, take your Sandoz Alendronate with plain water only as follows:

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

#### Do not take Sandoz Alendronate with:

- mineral water
- coffee or tea
- juice

Although it has not been tested, because of high mineral content, "hard water" may decrease absorption of Sandoz 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 Sandoz Alendronate .

**2. After taking your Sandoz Alendronate 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 Sandoz Alendronate at bedtime or before getting up for the day.**

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

6. Take one Sandoz Alendronate once a day, every day. If you miss a dose , just take one dose of Sandoz Alendronate on the morning after you remember. *Do not take two doses on the same day.* Return to taking one dose per day, as originally scheduled.

7. It is important that you continue taking Sandoz Alendronate for as long as your doctor prescribes it. Sandoz 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 Sandoz Alendronate therapy.

#### Why is it important to continue to take Sandoz Alendronate ?

It is important to take Sandoz 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 Sandoz 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.

## OVERDOSAGE

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.

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

### Missed dose:

If you miss a dose, just take one dose of Sandoz Alendronate on the morning after you remember. *Do not take two doses on the same day.* Return to taking one dose per day, as originally scheduled.

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

Sandoz Alendronate 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 Sandoz 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 patients continue to take Sandoz Alendronate 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 affect 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	
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		√	
<b>Rare</b>			
- 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			√
Persistent ear pain		√	

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

## HOW TO STORE IT

Store Sandoz Alendronate 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 Sandoz Alendronate and all medications safely away from children.**

## 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/adverse-reaction-reporting.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.*

## MORE INFORMATION

If you want more information about ACH-Alendronate:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by calling the sponsor Sandoz Canada Inc. at 1-800-361-3062

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## PART III: CONSUMER INFORMATION

### Pr Sandoz Alendronate Alendronate Sodium Tablets 70 mg alendronate once weekly dosage

This leaflet is part III of a three-part "Product Monograph" published when Sandoz 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 Sandoz Alendronate. Contact your doctor or pharmacist if you have any questions about the drug.

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

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

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

Each Sandoz Alendronate 70 mg contains alendronate sodium.

##### What the nonmedicinal ingredients are:

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

##### What dosage forms it comes in:

Sandoz Alendronate 70 mg tablets, a white to off-white, oval biconvex uncoated tablet with inscription '70' on one side and plain on the other side.

#### WARNINGS AND PRECAUTIONS

##### **Before you use Sandoz Alendronate 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 Sandoz Alendronate .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.

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 Sandoz Alendronate as these could be signs of bone damage in the ear.

#### **Use in pregnancy and breast-feeding**

Do not take Sandoz Alendronate if you are pregnant or breast-feeding.

#### **Use in children**

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

#### **Use in elderly**

Sandoz 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 Sandoz Alendronate ?**

There have been side effects reported with alendronate sodium that may affect your ability to drive or operate machinery. Individual responses to Sandoz 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 sodium if they are taken at the same time. You must wait at least one-half hour after taking Sandoz Alendronate before taking any other oral medication.

### **PROPER USE OF THIS MEDICATION**

#### Usual dose:

#### **How should I take Sandoz Alendronate once weekly?**

Your doctor has prescribed Sandoz Alendronate once weekly as tablets.

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

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

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

plain water.

Do **not** take Sandoz Alendronate with:

- mineral water
- coffee or tea
- juice

Although it has not been tested, because of high mineral content, "hard water" may decrease absorption of Sandoz 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 Sandoz Alendronate .**

**3. After taking your Sandoz Alendronate , 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 Sandoz Alendronate at bedtime or before getting up for the day.**

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

**7. If you miss a dose, just take one dose of Sandoz Alendronate 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.

**8. It is important that you continue taking Sandoz Alendronate for as long as your doctor prescribes it. Sandoz 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 Sandoz Alendronate therapy.

#### **Why is it important to continue to take Sandoz Alendronate ?**

It is important to take Sandoz 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 Sandoz 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.

## OVERDOSAGE

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 overdosage, contact a health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

### Missed dose:

If you miss a dose, just take one dose of Sandoz Alendronate 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

Sandoz Alendronate 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 **Sandoz 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 patients continue to take **Sandoz Alendronate** 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 affect 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	
<b>Uncommon</b>			
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			√
<b>Rare</b>			
Persistent ear pain		√	

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

## 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 Sandoz Alendronate and all medications safely away from children.**

## 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/adverse-reaction-reporting.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.*

If you want more information about ACH-Alendronate:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by calling the sponsor Sandoz Canada Inc. at 1-800-361-3062

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## MORE INFORMATION