

APO-ALENDRONATE TABLETS

Alendronate Sodium Trihydrate (70mg)

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What Apo-Alendronate is used for

Apo-Alendronate is used to treat osteoporosis in postmenopausal women (the time after a woman's menstrual periods have ceased completely).

How Apo-Alendronate works

Apo-Alendronate is a member of a class of non-hormonal drugs called bisphosphonates.

Bone undergoes a normal process of rebuilding that occurs continuously throughout your skeleton. This balanced process of removal of bone and forming bone keeps your skeleton healthy and strong.

Osteoporosis is a thinning and weakening of the bones which may result in broken bones, height loss, stooped posture and loss of mobility. It is common in women after menopause and may also occur in men. Apo-Alendronate prevents this loss of bone, also helps to rebuild normal bone and makes bone less likely to fracture.

Before you use Apo-Alendronate

- When you must not use it

Do not take Apo-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 (see section **Product description**)
- Your doctor has told you that you currently have low blood calcium.

- Have severe kidney problem

- Before you start to use it

Before you use Apo-Alendronate talk to your doctor or pharmacist if:

- If you have or have had any medical problems, including known kidney disease and about allergies.
- If you have any swallowing or digestive problems
- If you are suffering from cancer and/or taking corticosteroids. If you have any of these conditions, you should consider having a dental examination before starting Apo-Alendronate.
- If you plan to have a dental procedure.

Pregnancy and lactation

Do not take Apo-Alendronate if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Alendronate if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, particularly if you are taking any hormone or glucocorticoid medicines.

Some medicines are likely to interfere with the absorption of Apo-Alendronate if taken at the same time. These include:

- antacids, medicines used to treat indigestion
- calcium supplements

Therefore, take Apo-Alendronate at least 30 minutes before taking any of these or other medicines to make sure there is no problem with absorption.

Other medicines not listed above may also interact with Apo-Alendronate. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Apo-Alendronate

- How much to use

The usual dose of Apo-Alendronate is one tablet once a week. Choose the day of the week that best fits your schedule. Every week, take one Apo-Alendronate 70mg tablet on your chosen day.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Apo-Alendronate should not be given to children.

- When to use it

Use as directed by your doctor or pharmacist.

Instructions for use

Apo-Alendronate must be swallowed whole after getting up for the day and at least 30 minutes before the first food, beverage, or medication of the day with a full glass of water only. Do not take it at bedtime or before arising for the day.

Apo-Alendronate is effective only if taken when your stomach is empty. Do not take any food, medicines or drinks other than plain tap water (including mineral water) with Apo-Alendronate and 30 minutes after swallowing Apo-Alendronate. They are likely to reduce the absorption of Apo-Alendronate (see also Taking other medicines).

Do not chew or suck on a tablet of Apo-Alendronate. Mouth ulcers may occur if the tablet is chewed or dissolved in the mouth.

<p>Stay upright for at least 30 minutes after swallowing Apo-Alendronate. These actions will help make sure your dose of Apo-Alendronate reaches your stomach quickly and help reduce the potential for irritation to your food pipe.</p> <p>- <u>How long to use it</u></p> <p>Continue taking Apo-Alendronate for as long as your doctor recommends.</p> <p>Since it is not known how long you should take Apo-Alendronate, you should discuss the need to stay on this medication with your doctor periodically to determine if Apo-Alendronate is still right for you.</p> <p>- <u>If you forget to use it</u></p> <p>Consult your doctor or pharmacist on what you should do if you forget to use it.</p> <p>Take it first thing in the morning on the day after you remember the missed dose. If you forget to take this medicine first thing in the morning, do not take it later in the day. Wait until the next morning to take the medicine and skip the missed dose. Do not double up on the next dose to make up for the one missed.</p> <p>- <u>If you use too much (overdose)</u></p> <p>Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.</p> <p>If you take too much Apo-Alendronate, you may have an upset stomach, heartburn, or upper gastrointestinal events. Due to the risk of esophageal irritation, you should avoid vomiting and should sit upright at all time.</p>	<p>While you are using it</p> <p>- <u>Things you must do</u></p> <p>Take your medicine exactly as your doctor has told you.</p> <p>Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Alendronate.</p> <p>Tell your doctor immediately if you become pregnant while taking this medication.</p> <p>Make sure you are taking enough calcium and Vitamin D in your diet. Your doctor, pharmacist, or dietitian can tell you what foods you should eat, and whether you should take a supplement.</p> <p>- <u>Things you must not do</u></p> <p>Do not stop taking the medicine unless advised by your doctor.</p> <p>Do not take any new medicines without consulting your doctor or pharmacist.</p> <p>Do not give Apo-Alendronate to anyone else, even if they have the same symptoms or condition as you.</p> <p>- <u>Things to be careful of</u></p> <p><u>Driving and using machines</u></p> <p>This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.</p> <p>Side effects</p> <p>Like all medicines, Apo-Alendronate can cause side effects, although not everybody gets them.</p> <p>Tell your doctor if you notice any of the following and they worry you:</p> <ul style="list-style-type: none"> • Dizziness, headache • Nausea, vomiting • Bone, muscle or joint pain 	<p>Tell your doctor immediately if you notice any of the following:</p> <ul style="list-style-type: none"> • symptoms of an allergic reaction e.g. skin rash, itchiness, shortness of breath, swelling of hands, ankles or feet • Ulcers and inflammation in oesophagus • Jaw-bone problems, which may be associated with infection, and delayed healing after tooth extraction (tell both your doctor and dentist immediately) • Symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth <p>Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. Other side effects not listed above may also occur in some people.</p> <p>You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).</p> <p>Storage and Disposal of Apo-Alendronate</p> <p>- <u>Storage</u></p> <p>Keep out of the reach and sight of children.</p> <p>Store below 25°C.</p> <p>- <u>Disposal</u></p> <p>Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.</p> <p>Product Description</p> <p>- <u>What it looks like</u></p> <p>Apo-Alendronate 70 mg tablets are white, oval and biconvex tablets engraved with “APO” on one side and</p>
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"ALE70" on the other side .

- Ingredients

- Active ingredient
Alendronate sodium trihydrate
equivalent to 70 mg alendronic acid
70mg
- Inactive ingredients
Magnesium stearate, mannitol and
microcrystalline cellulose

- MAL number:

MAL 07031149A

Manufacturer

Apotex Inc.
150 Signet Drive
Weston Toronto Ontario
M9L 1T9 Canada

Product Registration Holder

Pharmaforte(M) Sdn Bhd
2, Jalan PJU 3/49,
Sunway Damansara,
47810 Petaling Jaya,
Selangor.

Date of revision

20/01/2016

Serial Number

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