

# APO-ALENDRONATE

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking APO-ALENDRONATE?

APO-ALENDRONATE contains the active ingredient alendronate sodium trihydrate. APO-ALENDRONATE is used to treat osteoporosis. It belongs to a group of medicines called bisphosphonates. Osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

For more information, see Section [1. Why am I taking APO-ALENDRONATE?](#) in the full CMI.

### 2. What should I know before I take APO-ALENDRONATE?

Do not take if you have ever had an allergic reaction to alendronate sodium trihydrate or any of the ingredients listed at the end of the CMI.

**Alendronate sodium trihydrate can irritate or burn your mouth or food pipe (also called the oesophagus).** The chances of this happening should be reduced if you follow the instructions for taking APO-ALENDRONATE in this leaflet.

Do not take this medicine if you have the following medical conditions: certain disorders of the food pipe (oesophagus), conditions that cause difficulty in swallowing, unable to stand or sit upright for at least 30 minutes, low blood calcium (hypocalcemia).

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take APO-ALENDRONATE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-ALENDRONATE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take APO-ALENDRONATE?

- The usual dose is one 70 mg tablet once a week.
- **Swallow one tablet whole with a full glass of plain water only.** It is important to take APO-ALENDRONATE with plain water only, not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea will reduce the effect of alendronate sodium trihydrate by interfering with its absorption into the body.
- **Do not crush, chew or suck on a tablet of APO-ALENDRONATE.** Mouth ulcers or irritation to your mouth or food pipe (oesophagus) may occur if the tablet is crushed or chewed or dissolved in the mouth.

More instructions can be found in Section [4. How do I take APO-ALENDRONATE?](#) in the full CMI.

### 5. What should I know while taking APO-ALENDRONATE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking APO-ALENDRONATE.</li><li>• If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking the tablets and call your doctor.</li><li>• Tell your doctor immediately if you develop pain in your hip or thigh. This may be a sign that you have a stress fracture of your hip or upper thigh bone.</li><li>• Tell your doctor immediately if you break a bone, or you develop bone, muscle or joint pain. Long term treatment with this medicine may cause stress fractures (repetitive trauma) or low energy fractures (falls from standing). If you develop new or unusual pain in the hip, thigh or any other bone, contact your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li><li>• Do not take your medicine to treat any other complaint unless your doctor tells you to.</li><li>• Do not stop taking your medicine, or change the dosage, without first checking with your doctor.</li></ul>

<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how this medicine affects you. APO-ALENDRONATE can make some people feel giddy or dizzy or have blurred vision.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor you drink alcohol. Drinking alcohol excessively on a regular basis may increase your risk of developing osteoporosis. You may need to cut down on the amount of alcohol you drink.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your medicine in a cool dry place where the temperature stays below 25°C.</li> <li>• Keep the tablets in the blister pack until it's time to take them.</li> </ul>

For more information, see Section [5. What should I know while taking APO-ALENDRONATE?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include stomach complaints, such as pain, wind, an uncomfortable feeling in the stomach, belching after eating, heartburn, nausea, vomiting, unusual taste, hair loss, constipation, diarrhoea, headache, aching muscles, joints or bones, flu-like symptoms, such as aching muscles, generally feeling unwell (rarely with fever). Swollen joints, dizziness or spinning sensation, unusual tiredness or weakness, dry skin, swelling of the hands, ankles or feet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# APO-ALENDRONATE

Active ingredient: *alendronate sodium trihydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-ALENDRONATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-ALENDRONATE.**

**Where to find information in this leaflet:**

- [1. Why am I taking APO-ALENDRONATE?](#)
- [2. What should I know before I take APO-ALENDRONATE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APO-ALENDRONATE?](#)
- [5. What should I know while taking APO-ALENDRONATE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking APO-ALENDRONATE?

**APO-ALENDRONATE contains the active ingredient alendronate sodium trihydrate.** Alendronate sodium trihydrate belongs to a group of medicines called bisphosphonates.

APO-ALENDRONATE is used to treat osteoporosis.

Osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

### Understanding Bone

Bone is living, growing tissue. Throughout life, our bodies are breaking down old bone and rebuilding new bone in a continuous cycle.

### How it Works

Alendronate sodium trihydrate works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone.

Alendronate sodium trihydrate helps prevent the loss of bone and helps to rebuild bone, making bone less likely to break. This helps to prevent or reverse the progression of osteoporosis.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed APO-ALENDRONATE for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of APO-ALENDRONATE in children.

## 2. What should I know before I take APO-ALENDRONATE?

### Warnings

**APO-ALENDRONATE can irritate or burn your mouth or food pipe (also called the oesophagus).**

The chances of this happening should be reduced if you follow the instructions for taking APO-ALENDRONATE in this leaflet.

### Do not take APO-ALENDRONATE if:

- you are allergic to alendronate sodium trihydrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue, throat or other parts of the body
  - itching or hives on the skin.
- you have the following medical conditions:
  - certain disorders of the food pipe (oesophagus)
  - conditions that cause difficulty in swallowing
  - unable to stand or sit upright for at least 30 minutes
  - low blood calcium (hypocalcemia).
- you are pregnant, plan to become pregnant or are breastfeeding. APO-ALENDRONATE has not been studied in pregnant or breast-feeding women.

### Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - serious kidney disease
  - swallowing or digestive problems, such as stomach pain, reflux, ulcers, Barrett's oesophagus
  - low vitamin D levels
  - diabetes
  - alcohol abuse
  - any bone fractures.
- have any of the following, which may increase your risk of getting jaw bone problems:

- cancer
- radiotherapy, chemotherapy treatment
- taking angiogenesis inhibitors
- problems with your teeth, mouth or gums
- anaemia
- problems with blood clotting
- infection
- you are a smoker
- you are taking steroids
- you are planning to have any dental procedures such as tooth extraction or other oral surgery
- you don't regularly look after your teeth or see a dentist.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with APO-ALENDRONATE if taken at the same time:**

- antacids
- calcium supplements
- non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen.

Take APO-ALENDRONATE at least 30 minutes before taking any of these or other oral medicines.

You may take aspirin while you are being treated with APO-ALENDRONATE. However, both aspirin and APO-ALENDRONATE may increase the chance of stomach upsets.

Other medicines not listed above may also interact with APO-ALENDRONATE.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-ALENDRONATE.**

### 4. How do I take APO-ALENDRONATE?

#### How much to use

- The usual dose is one 70 mg tablet once a week.
- **Swallow one tablet whole with a full glass of plain water only.**

It is important to take APO-ALENDRONATE with plain water only, not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of alendronate sodium trihydrate by interfering with its absorption into the body.

- **Do not crush, chew or suck on a tablet of APO-ALENDRONATE.**  
Mouth ulcers or irritation to your mouth or food pipe (oesophagus) may occur if the tablet is crushed or chewed or dissolved in the mouth.
- **Stay upright for at least 30 minutes after swallowing the tablet and do not take any food, medicines or drinks other than plain water during this time. Do not lie down immediately after swallowing it.**

It is important to stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing your tablet. It is also very important to stay upright until after you have eaten your first food of the day. These actions will help make sure the tablet reaches your stomach quickly and help reduce the potential for irritation to your food pipe (oesophagus).

- Follow the instructions provided by your doctor or pharmacist and take APO-ALENDRONATE until your doctor tells you to stop.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

#### When to take APO-ALENDRONATE

- Choose a day of the week that best fits your schedule. Every week take one tablet on your chosen day.
- Take APO-ALENDRONATE immediately after getting up for the day. Do not take it at bedtime, or before you get up in the morning.

APO-ALENDRONATE is effective only if taken when your stomach is empty. Food, drinks other than plain water and other medicines will lessen the effect of alendronate sodium trihydrate by interfering with its absorption into the body.

#### If you forget to take APO-ALENDRONATE

APO-ALENDRONATE should be taken regularly at the same time each week. If you miss a tablet at the usual time, take one tablet in the morning after you remember.

**Do not take two tablets on the same day.**

This may increase the chance of you getting an unwanted side effect.

Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### If you take too much APO-ALENDRONATE

If you think that you have taken too much APO-ALENDRONATE, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

**If you take too many tablets at one time, drink a full glass of milk or take some antacids. Do not make yourself vomit and do not lie down.**

**If you take too much APO-ALENDRONATE, you may have an upset stomach, heartburn, throat or stomach pain or problems swallowing.**

## **5. What should I know while taking APO-ALENDRONATE?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking the tablets and call your doctor.
- develop pain in your hip or thigh. This may be a sign that you have a stress fracture of your hip or upper thigh bone.
- break a bone, or you develop bone, muscle or joint pain. Long term treatment with this medicine may cause stress fractures (repetitive trauma) or low energy fractures (falls from standing). If you develop new or unusual pain in the hip, thigh or any other bone, contact your doctor. Your doctor will:
  - evaluate your condition if they suspect you have developed a fracture
  - examine the cause of the stress fracture and provide appropriate care
  - pause your treatment depending on your condition.
- Tell your doctor and dentist if you require a dental procedure, or if you develop toothache, jaw pain, delayed healing or infection.
- Tell your doctor if you are going to have surgery.
- Keep up good oral hygiene practices by:
  - regularly brushing teeth
  - cleaning between teeth with floss or interdental cleaner
  - eating a balanced diet
  - visiting your dentist regularly.
- Make sure you receive enough calcium and Vitamin D in your diet. Your doctor, dietician or pharmacist can tell you what foods you should eat, and whether you should take a supplement.

- Patients who have history of kidney stones or high level of calcium in the urine, may require special dietary modifications.
- Remind any doctor, dentist or pharmacist you visit that you are using APO-ALENDRONATE.

### **Things you should not do**

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take your medicine to treat any other complaint unless your doctor tells you to.
- Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

### **Things that would be helpful for your osteoporosis**

Talk to your doctor or pharmacist about the following self-help measures for more information:

- Exercise can help to build and maintain strong bones.
- Eat a balanced diet, ensuring you have enough calcium and Vitamin D in your diet.
- Smoking may increase the rate at which you lose bone, increasing your risk of fracture. You may need to stop or cut down on smoking.
- Drinking alcohol excessively on a regular basis may increase your risk of developing osteoporosis. You may need to cut down on the amount of alcohol you drink.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how APO-ALENDRONATE affects you.**

APO-ALENDRONATE can make some people feel giddy or dizzy or have blurred vision.

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Drinking alcohol excessively on a regular basis may increase your risk of developing osteoporosis. You may need to cut down on the amount of alcohol you drink.

### **Looking after your medicine**

- Keep your medicine in blister pack until it is time to take it. If you take your medicine out of the pack it may not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Stomach complaints, such as pain, wind, an uncomfortable feeling in the stomach, belching after eating, heartburn, nausea, vomiting.</li> <li>• Unusual taste.</li> <li>• Hair loss.</li> <li>• Constipation, diarrhoea.</li> <li>• Headache.</li> <li>• Aching muscles, joints or bones.</li> <li>• Flu-like symptoms, such as aching muscles, generally feeling unwell (rarely with fever).</li> <li>• Swollen joints.</li> <li>• Dizziness or spinning sensation.</li> <li>• Unusual tiredness or weakness.</li> <li>• Dry skin.</li> <li>• Swelling of the hands, ankles or feet.</li> <li>• Sour/Bitter Taste into the throat or mouth.</li> <li>• Heartburn.</li> <li>• Non-cardiac chest pain.</li> <li>• Chronic cough, wheezing, and hoarseness.</li> <li>• Bad breath, nausea, and difficulty swallowing.</li> <li>• Constipation.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Jaw-bone problems, infection, delayed healing after teeth are pulled out or other work that involves drilling into the jaw (tell both your doctor and dentist immediately).</li> <li>• Skin rash or redness of the skin sometimes made worse by sunlight, itchiness.</li> <li>• Mouth ulcers.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

<ul style="list-style-type: none"> <li>• Blurred vision, pain or redness in the eye.</li> <li>• Muscle cramps or spasms or tingling sensation in the fingers or around the mouth (signs of low blood calcium levels).</li> <li>• Difficulty or pain when swallowing; painful mouth; chest pain; new or worsening heartburn (may be due to irritation or ulceration of the mouth or food pipe. Stop taking the tablets and tell your doctor immediately).</li> </ul>	<p><b>these serious side effects.</b></p>
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### Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>• Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; rash, itching or hives on the skin; severe skin reactions (e.g. severe rash and/or peeling layers of skin) (signs of an allergic reaction).</li> <li>• Black tar-like and/or bloody stools (may indicate severe stomach or duodenal ulcers).</li> <li>• Pain in your hip or thigh bone (signs of stress fractures of the upper thigh or hip).</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What APO-ALENDRONATE contains

<b>Active ingredient (main ingredient)</b>	Alendronate sodium trihydrate
<b>Other ingredients (inactive ingredients)</b>	magnesium stearate mannitol microcrystalline cellulose

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What APO-ALENDRONATE looks like

APO-ALENDRONATE is a white oval biconvex tablet, engraved APO on one side and ALE 70 on the other side.

Contained in blister pack of 4 tablets. AUST R 123863.

### Who distributes APO-ALENDRONATE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St,

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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