

APO-Alendronate Once Weekly

Contains the active ingredient, alendronate (as alendronate sodium)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

It is particularly important that you read the sections "When to take it" and "How to take it" before you take this medicine.

This leaflet answers some common questions about alendronate. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on your medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Alendronate Once Weekly. It contains the active ingredient, alendronate (as alendronate sodium).

It is used to treat osteoporosis.

Understanding Bone

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

Until our late 20's, while bones are still developing, we gain bone by building more than we lose. From then until about age

35 the process is usually in balance, so that the amount of bone lost is about equal to the amount that is replaced.

After about age 35 this balance is disturbed, with bone loss occurring at a slightly faster rate than it can be replaced. In women, after menopause, hormonal changes cause bone loss at an even faster rate.

When bone loss is excessive, bones can become thinner and weaker, and therefore are more likely to break.

Osteoporosis

"Osteo" means bone, and "porosis" means something that has holes in it, like a sponge.

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

Osteoporosis is common in post-menopausal women. The menopause occurs when the ovaries virtually stop producing the female hormone, oestrogen, or are removed (which may occur, for example, at the time of a hysterectomy). At this time, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Osteoporosis also occurs in men but is less common than in women.

Osteoporosis can also occur in people receiving corticosteroid medicines. If taken in high doses or for a long period of time,

corticosteroid medicines can cause bone to be removed faster than it is formed. This causes loss of bone and therefore, bones become weaker and are more likely to break.

Maintaining bone mass and preventing further bone loss are important to keep your skeleton healthy.

Early on, osteoporosis usually has no symptoms. However, if left untreated it can result in broken bones, also called fractures. 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 it works

Alendronate belongs to a group of medicines called bisphosphonates.

In osteoporosis, it works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone.

Alendronate not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, alendronate prevents or reverses the progression of osteoporosis.

Alendronate starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

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

Your doctor may have prescribed alendronate for another reason.

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

There is no evidence to show that this medicine is addictive.

Use in children

Children should not take alendronate, as there is not enough information to recommend the use of this medicine in children.

Before you take this medicine

You should know that 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 alendronate in this leaflet.

When you must not take it

Do not take this medicine if:

- you have certain disorders of the food pipe (oesophagus) including those that cause difficulty in swallowing
- you are unable to stand or sit upright for at least 30 minutes
- your doctor has told you that you currently have low blood calcium (hypocalcaemia)
- your dentist advises you to consult your doctor first
- it has passed the expiry date (EXP) printed on the pack
- the packaging is torn, shows signs of tampering or it does not look quite right
- you have had an allergic reaction to alendronate or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, 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.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

In addition, women who are pregnant or breast-feeding should not take this medicine, because alendronate has not been studied in pregnant or breast-feeding women.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- serious kidney disease
- swallowing or digestive problems, such as stomach pain, reflux or ulcers
- low vitamin D levels
- diabetes
- alcohol abuse
- any bone fractures

3. You currently have any of the following, which may increase your risk of getting jaw bone problems:

- cancer
- radiotherapy or chemotherapy treatment
- 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.
- 4. You are currently pregnant or breastfeeding or you plan to become pregnant or breast-feed.**

Alendronate is intended for use in postmenopausal women. You should not take alendronate if you are or think you may be pregnant, or if you are breast-feeding.

- 5. You are planning to have surgery.**
- 6. You are currently receiving or are planning to receive dental treatment.**
- 7. You are taking or are planning to take any other medicines.**

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines are likely to interfere with the absorption of alendronate if taken at the same time.

These include:

- antacids (such as Algicon[®], Almacarb[®], Alu-tab[®], Amphojel[®], De witt's[®] antacid, Eno[®] powder, Gastrobom[®], Gastrogel[®], Gelusil[®], Meracote[®], Mucaine[®], Mylanta[®], Rennie[®], Salvital[®], Simeco[®], Titalac[®])
- calcium supplements
- vitamins.

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

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

Other medicines not listed above may also interact with alendronate.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose of this medicine is one 70 mg tablet once a week.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow one tablet whole with a full glass of plain water only.

It is important to take 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 by interfering with its absorption into the body.

Do not crush, chew or suck on a tablet of 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 tap 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).

When to take it

Choose a day of the week that best fits your schedule. Every week take one tablet on your chosen day.

Take alendronate immediately after getting up for the day. Do not take it at bedtime, or before you get up in the morning.

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 by interfering with its absorption into the body.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Alendronate can only prevent or treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it every week.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you miss a tablet take one tablet on 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 (overdose)

If you think that you or anyone else may have taken too much of this medicine immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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 alendronate, you may have an upset stomach, heartburn, throat or stomach pain or problems swallowing.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn (stop taking the tablets and call your doctor)
- you develop pain in your hip or thigh (tell them immediately). This may be a sign that you have a stress fracture of your hip or upper thigh bone. This has been known to occur very rarely in patients who have been taking alendronate for some time.
- you break a bone (have a fracture)
- you develop bone, muscle or joint pain
- you require a dental procedure (tell your dentist also)
- you develop toothache, jaw pain, delayed healing or infection, as alendronate may cause jaw bone problems in some people. (tell your dentist and doctor immediately)
- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed
- you are about to have any blood tests

- 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 and visiting your dentist regularly.

Make sure you are taking 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.

Things you must not do

Do not:

- give this medicine to anyone else, even if their symptoms seem similar to yours.
- take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- stop taking your medicine, or change the dosage, without first checking with your doctor.

Things that would be helpful for your osteoporosis

Some self help measures suggested below may help your osteoporosis. Talk to your doctor or pharmacist about these measures and for more information:

- **Exercise**

Exercise can be helpful in building and maintaining strong bones. Regular exercise such as a brisk walk is a good idea. Talk to your doctor before you begin any exercise program.

- **Diet**

Eat a balanced diet. You may need to increase the amount of calcium and Vitamin D in your diet by eating foods rich in these vitamins, or taking calcium and Vitamin D supplements. Your doctor, dietician or pharmacist will advise you.

- **Smoking**

Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture. Your doctor may ask you to stop smoking or at least cut down.

- **Alcohol**

Your doctor may advise you to cut down the amount of alcohol you drink. If you drink excessively on a regular basis, you may increase your risk of developing osteoporosis.

Things to be careful of

Be careful while driving or operating machinery until you know how this medicine affects you. Alendronate can make some people feel giddy or dizzy or have blurred vision.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking alendronate or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects.

You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- stomach pain, gas in the stomach or bowel, wind
- an uncomfortable feeling in the stomach or belching after eating (also called dyspepsia); or heartburn or acid regurgitation
- feeling sick (nausea), vomiting
- unusual taste

- hair loss
- constipation, diarrhoea
- headache
- aching muscles, joints or bones
- flu-like symptoms, such as aching muscles, generally feeling unwell, and rarely, fever
- swollen joints
- dizziness or spinning sensation
- unusual tiredness or weakness
- dry skin
- swelling of the hands, ankles or feet.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- Jaw-bone problems, which may include infection, and delayed healing after teeth are pulled out or other work that involves drilling into the jaw (tell both your doctor and dentist immediately)
- skin rash or redness of the skin, sometimes made worse by sunlight; itchiness

- mouth ulcers
- blurred vision, pain or redness in the eye
- symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth

The following side effects, which may be due to irritation or ulceration of the mouth or food pipe (stop taking the tablets and tell your doctor immediately):

- difficulty or pain when swallowing
- painful mouth
- chest pain
- new or worsening heartburn.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- symptoms of bleeding from the stomach or intestine, such as black tar-like and/or bloody stools. These may be complications of severe stomach or duodenal ulcers
- signs of stress fractures of the upper thigh or hip, such as pain in your hip or thigh bone

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to alendronate, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms
- severe skin reactions (e.g. severe rash and/or peeling layers of skin)

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Apo-Alendronate Once Weekly looks like

Apo-Alendronate Once Weekly

White, oval biconvex tablet, engraved APO on one side and ALE 70 on the other side.

Contained in blister packs of 4 tablets.

Ingredients

Each tablet contains 70 mg of alendronic acid (as alendronate sodium trihydrate) as the active ingredient.

It also contains the following inactive ingredients:

- magnesium stearate
- mannitol
- cellulose-microcrystalline.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Alendronate Once Weekly 70 mg Tablets:

Blister packs

AUST R 123863.

Sponsor

Apotex Pty Ltd

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