

ALENDROBELL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Alendrobell (alendronate).

It does not contain all the available information.

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

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

If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine. **You may need to read it again**

What Alendrobell is used for

Alendrobell contains alendronate tablets.

Alendrobell is used to treat osteoporosis.

This condition is caused by changes in the way bone is normally maintained.

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 20s, 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 postmenopausal 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 does Alendrobell work?

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. **Alendrobell** not only helps prevent the loss of bone but also actually helps to rebuild bone and makes bone less likely to fracture. Thus, Alendrobell 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.

Alendronate belongs to a group of non-hormonal medicines called bisphosphonates.

Before you take Alendrobell

You should know that **Alendrobell** can irritate or burn the food pipe in some people. The chances of this happening should be reduced if you follow the precautions and instructions for taking **Alendrobell**.

When you must not take it

You have an allergy to **Alendrobell** or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the tongue or face.

Do not take if any of the following applies to you:

- You have certain disorders of the food pipe (also called 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

Do not take Alendrobell after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well or may cause harm. Do not take **Alendrobell** if the tablets do not look quite right.

Do not take Alendrobell if the packaging is torn or shows signs of tampering.

Tell your doctor if you have allergies to:

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

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

Alendrobell has not been studied in pregnant or breast-feeding women.

Tell your doctor if you are pregnant or planning to become pregnant.

Like many other medicines, **Alendrobell** may affect your

developing baby if you take it during pregnancy.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Your doctor will discuss the possible risks and benefits of using **Alendrobell** during breastfeeding.

Tell your doctor if:

- you plan to become pregnant or breast-feed
- you have any medical conditions, especially the following:
- kidney disease
- swallowing or digestive problems, such as ulcers
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you have gum disease
- you have a planned dental extraction

A dental examination should be considered before you start treatment with **Alendrobell** if you have any of the conditions listed below.

- you have cancer
- you are undergoing chemotherapy or radiotherapy
- you are taking steroids
- you don't receive routine dental care
- you have gum disease
- you suffer from anaemia
- you have a blood clotting disorder

If you suffer from any of the above, your doctor may recommend that you undergo dental treatment to prevent jaw-bone problems, before you start your treatment with **Alendrobell**.

Your doctor may decide to discontinue **Alendrobell** treatment if you are scheduled for oral surgery.

If you have not told your doctor about any of the above, tell him/her before you take **Alendrobell**.

There is no change in the dose of **Alendrobell** when given to elderly patients.

Do not give **Alendrobell** to a child. **Alendrobell** has not been studied in children

Avoid alcoholic beverages until you have discussed their use with your doctor.

Tell your doctor if you plan to have blood/urine test.

If you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicine you are taking.

You will need to undergo blood tests for monitoring your sugar levels at regular intervals.

If you have not told your doctor about any of the above, tell them before you take Alendrobell.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Some medicines are likely to interfere with the absorption of Alendrobell 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, Titralac
- calcium supplements
- vitamins

Therefore, take **Alendrobell** at least 30 minutes before taking any of these or other medicines to make sure there is no problem with absorption. Check with your doctor or pharmacist if you are not sure whether you are taking an antacid.

You can take aspirin while you are being treated with **Alendrobell**. However, both aspirin and

Alendrobell may increase the chance of stomach upsets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking **Alendrobell**.

These medicines may be affected by **Alendrobell**, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given **Alendrobell** with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Alendrobell.

How Alendrobell is given

How much to take

Take Alendrobell 70 mg only when prescribed by your doctor.

The usual dose of Alendrobell 70 mg is one tablet (containing 70 mg of alendronate) once a week.

Choose the day of the week that best fits your schedule. Every week, take one tablet of Alendrobell 70mg on your chosen day.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in the leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When and how to take it

Take Alendrobell 70mg, once a week, after getting up for the day on your chosen day and at least 30 minutes before taking your first food, beverage, or any other medication. Do not take it at bedtime.

Take Alendrobell 70 mg on the same day of the week every week.

Swallow Alendrobell whole with a full glass of plain water only.

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

Stay upright for at least 30 minutes after swallowing Alendrobell 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 your tablet reaches your stomach quickly and help reduce the potential for irritation to your food pipe (oesophagus).

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

Do not chew or suck on a tablet of Alendrobell.

Mouth ulcers may occur if the tablet is chewed or dissolved in the mouth.

How long to take it

It is important that you continue taking **Alendrobell** for as long as your doctor prescribes. **Alendrobell** 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.

Do not let yourself run out of medicine over the weekend or on holidays.

If you forget to take it

If you miss a tablet, take one on the morning after you remember.

Do not take two tablets on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you are not sure what to do, talk to your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Alendrobell. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep these telephone numbers handy

If you take too many tablets at one time, drink a full glass of milk. Do not induce vomiting. Do not lie down.

While you are using Alendrobell

Things you must do

Take Alendrobell Tablets exactly as your doctor tells you to.

If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Alendrobell and call your doctor.

Visit your doctor regularly for check ups.

If you become pregnant while taking Alendrobell, stop taking the tablets and tell your doctor.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Alendrobell.

Make sure you have an adequate intake of calcium in your diet.

Your doctor, dietician or pharmacist can tell you what foods you should eat.

Appropriate preventative dental care and oral hygiene, as recommended by the dentist, should be followed during treatment.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Alendrobell .

Tell your doctor if you are to undergo any blood or urine test.

Things you must not do

Do not give Alendrobell to anyone else, even if they have the same condition as you.

Do not use alendronate to treat other complaints unless your doctor tells you to.

Do not stop taking Alendrobell, or change the dosage, without checking with your doctor.

Be careful driving or operating machinery until you know how Alendrobell affects you.

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 - 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 in your diet by eating calcium-rich foods or taking a calcium supplement. Your doctor will advise you.
- 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Alendrobell.

Alendrobell helps most people with osteoporosis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach pain, gas in the stomach or bowel, wind
- an uncomfortable feeling in the stomach or belching after eating, also called dyspepsia, or heartburn
- feeling sick (nausea), vomiting
- constipation, diarrhoea
- headache, dizziness
- aching muscles, joints and/or bones, which rarely can be severe
- flu-like symptoms, typically at the start of treatment, such as aching muscles, generally feeling unwell, and rarely, fever.
- swelling of hands and feet

Most of these are the more common side effects of Alendrobell. For the most part, these have been mild.

Tell your doctor immediately if you notice any of the following

- 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.
- Swelling or pain in the jaw with/without infections of the gums/teeth that take a long time to heal. Alendrobell may cause jaw-bone problems in some people. Jaw-bone problems may include infection and delayed healing after teeth are pulled out or other work that involves drilling into the jaw.

These side effects are rare, and very rarely, may be serious

If any of the following happen, stop taking Alendrobell and tell your doctor immediately:

- difficulty or pain upon swallowing
- chest pain
- new or worsening heartburn

These side effects may be due to irritation or ulceration of the food pipe. They may worsen if you continue taking the tablets.

Rarely, these side effects may be serious.

Tell your doctor immediately or go to Emergency department at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- severe skin reactions
- black tar-like and/or bloody stools

These are very serious side effects. You may need urgent medical attention or hospitalization. All these side effects are very rare.

If you have the swelling described above, you may be having a serious allergic reaction to Alendrobell.

Uncommon episodes of irregular heartbeat have been reported. Rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by Alendrobell.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Alendrobell is not addictive.

After using Alendrobell

Storage

Keep this medicine where young children cannot reach it.

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the bottle or the blister pack they may not keep well.

Keep your Alendrobell in a cool, dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink.

Do not leave it in the car on hot days.

Disposal

If your doctor tells you to stop taking Alendrobell or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Alendrobell 70mg tablets are available in a pack of 4 tablets.

Alendrobell 70mg are white to off-white circular tablets, debossed with

“A” on one side and “4” on other side.

Ingredients

Active ingredient:

Alendronate sodium

Inactive ingredients

Mannitol

Croscarmellose sodium

Magnesium stearate

Purified Talc

Colloidal Anhydrous Silica

Sponsor

Alendrobell 70mg Tablets are supplied in Australia by:

Generic Health Pty Ltd
Level 1, 1102Toorak Road
Camberwell VIC 3124

Australian Registration Number

Alendrobell 70mg tablet blister pack: AUST R 130163

Alendrobell 5mg tablet blister pack: AUST R 130160 *

Alendrobell 10mg tablet blister pack: AUST R 130162 *

* Not marketed

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