

medicineupdate

Asking the right questions about new medicines

Alendronate for osteoporosis – preventing fractures in people with very fragile bones (low bone mineral density).

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get to know your medicines

to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon-Fri 9am-6pm EST – cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) for this medicine (available from your doctor or pharmacist, the consumer section at www.nps.org.au, or from the manufacturer).



National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

Remember that risks and benefits differ between medicines and from person to person.

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

1.
**What this
medicine is**

Active ingredient: **Alendronate** (pronounced 'a-LEN-drun-ATE')

Brand names: **Fosamax Once Weekly**
Fosamax Plus
Alendro Once Weekly

**The active ingredient
is the chemical in the
medicine that makes
the medicine work.**

Fosamax Once Weekly and Alendro Once Weekly contain alendronate only.

Fosamax Plus contains two active ingredients - alendronate and vitamin D3 .

Alendronate is a type of medicine called a bisphosphonate ('bis-fos-fo-nate').

Bisphosphonates are used to treat fragile bones (osteoporosis) and prevent fractures (broken bones).

Vitamin D is an essential substance for forming and maintaining strong bones.

2. What this medicine treats

Osteoporosis is a condition which causes bones to become fragile and brittle. If you have osteoporosis you are at risk of fractures, most commonly in the hips, spine (backbone) and wrist. These fractures can lead to long-term pain and the loss of independence.

Osteoporosis is more common in women, especially after menopause, but it can occur in men. Osteoporosis may also sometimes be caused by long-term use of some corticosteroid medicines, such as prednisolone, used for asthma and some rheumatic conditions.

Alendronate works by slowing bone thinning and allowing new bone to rebuild and strengthen. Bone strength is usually measured by a Bone Mineral Density (BMD) scan, which indicates the amount of calcium in your bones. A BMD scan is sometimes called a DXA scan.

This scan is quick and painless, like an X-ray. A BMD scan measures the density of your bones and compares the result to the bone density of an average young adult. The result is called a T-score. If you have osteoporosis your T-score will be minus 2.5 or lower. The lower your T-score the greater your risk of fracture, that is, a score of minus 3 is worse than a score of minus 2.5. Treatment with alendronate can increase your BMD and reduce your risk of breaking a bone.

However, a low BMD is not the only thing that determines your risk of fracturing (breaking) a bone. There are other risk factors for fracture too. We discuss some of the ways you can reduce your risk of fracture in Section 9: "Other ways to help this condition".

The most important risk factors, besides a low BMD, are:

- a previous fracture (broken bone) – if you have already had a fracture caused by osteoporosis you have a greater risk of more fractures.
- advanced age – an older person with a low BMD is at a greater risk of fracture than a young person with the same low BMD.

For this reason, people who have already suffered a fracture caused by osteoporosis, have a low BMD, and/or are over 70 years of age will benefit the most from treatment with a medicine for osteoporosis.

Thin and fragile bones are usually due to osteoporosis.

Bone Mineral Density (BMD) tests measure how thin bones are.

3. Other medicines available for this condition

Other medicines are available in Australia for the treatment of osteoporosis. Some of these are also bisphosphonates:

- Risedronate – brand name 'Actonel'
- Disodium etidronate – brand name 'Didrocal'.

Others are not:

- Raloxifene — brand name 'Evista'
- Strontium — brand name 'Protos'.

Some medicines for osteoporosis can only be prescribed for you on the Pharmaceutical Benefits Scheme (PBS) after you have had a fracture caused by osteoporosis. People who have already suffered a fracture are at the greatest risk of further fractures and therefore they get the most benefit from these medicines.

However, as of 1 April 2007, you may be eligible to receive alendronate on the PBS if you have osteoporosis but have not yet had a fracture. To qualify, you must be over 70 years of age and have had a Bone Mineral Density scan that shows that you have fragile bones (see Section 9: "Who can be prescribed this medicine on the PBS"). Alternative medicines are risedronate (Actonel) and strontium (Protos).

Hormone replacement therapy (HRT) was used in the past to prevent fractures in women with osteoporosis. However, HRT can slightly increase the risk of heart disease, stroke and breast cancer, so it is now only recommended for the short-term treatment of menopausal symptoms.

Calcium and vitamin D are also important for healthy bones. If you don't have enough calcium in your diet your doctor may recommend that you take calcium supplements. If you are unwell from any condition which means you cannot get outdoors much, or are dark-skinned or need to cover your head and body for cultural reasons, you may also need a vitamin D supplement. However, calcium and vitamin D alone are probably not enough to prevent fractures in people who have had a previous fracture.

Talk with your doctor about all of the treatment options for osteoporosis.

4. How well this medicine works compared with other medicines

A number of osteoporosis medicines, including alendronate, have been shown in clinical research trials to reduce the risk of new fractures in people who have already suffered a fracture as a result of osteoporosis. But, as yet, alendronate is one of the few medicines where there is good evidence to show that it can also prevent fractures in people with osteoporosis who have not yet suffered a fracture.

Alendronate was compared with a placebo (an inactive or "sugar" tablet) in two large clinical trials and found to reduce the risk of fracture.

1. In the first trial, the subjects were postmenopausal women with osteoporosis who had already had a fracture of the spine detected on x-ray.

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A clinical trial is a research study conducted with patients, which tests out a drug or other intervention to assess its effectiveness and safety.

For more information on clinical trials see Section 10: "How new medicines are tested and approved for use in Australia".

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4. **How well this medicine works compared with other medicines**

In this trial, 2027 women aged 55–81 years were followed up for 3 years. Approximately half the women received alendronate and the rest received a placebo. Amongst women who were treated with alendronate, 8% had a new spinal fracture detected by x-ray, compared with 15% of women who received the placebo. Alendronate also reduced the risk of other fractures of the spine, hip and wrist.

2. In the second trial the subjects were postmenopausal women who had not yet had a fracture but who were at high risk of doing so because of low bone mineral density.

This trial included over 4200 women, aged 54–81 years, who were followed up for four years. In women with low BMD (T score \leq -2.5), alendronate reduced the percentage of women who had any fracture from 20% to 13% and the percentage who had spinal fractures on x-ray was reduced from 6% to 3%, when compared with the placebo.

It is important to note that alendronate cannot prevent all fractures in people with osteoporosis. In addition, most of the women in the alendronate trials did not have enough calcium in their diet and therefore also needed to take calcium and vitamin D supplements. You should therefore ask your doctor if you need to take these supplements and also consider any other changes you could make to your lifestyle to reduce your risk of breaking a bone (see Section 9: "Other ways to help this condition"). Nonetheless it may not be possible to prevent every fracture.

5. **Important side effects to consider**

All medicines can have side effects. Sometimes the side effects are serious but most of the time they are not.

Problems with alendronate can range from nausea, vomiting and diarrhoea to more serious problems, such as inflammation and ulcers of the oesophagus (the tube which allows the passage of food from the throat to the stomach) and problems with the jaw.

The serious side effects to consider when deciding whether to use alendronate — or any other bisphosphonate — are oesophagus and rare jaw problems.

Because alendronate can irritate the oesophagus, you should not take this medicine if you:

- are unable to stand or sit upright for at least 30 minutes after taking the tablet, and/or
- have active stomach or oesophagus problems, such as ulcers, chronic heartburn or difficulty swallowing.

Rarely, bisphosphonates can cause weakening of bone in the jaw. Jaw problems that might occur include delayed healing and infection, often after dental work or sores in the mouth (such as those caused by dentures). Jaw problems have mostly occurred in cancer patients receiving high dose injections of bisphosphonates, but they have very occasionally been reported with alendronate tablets.

Fortunately, these side effects can generally be avoided if you take some sensible precautions (see Section 6: "How to reduce your risk of side effects").

For a complete list of possible side effects, see the consumer medicine information (CMI).

Talk to your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

6. How to reduce your risk of side effects

Stomach and oesophagus problems

Do not take alendronate if:

- you are unable to stand or sit upright for at least 30 minutes after taking the tablet
- you have active stomach or oesophagus problems, such as ulcers, heartburn or difficulty swallowing.

Let your doctor know if you are taking anti-inflammatory medicines for joint or muscle pain, as these medicines may increase the risk of oesophagus problems when taken with alendronate.

To reduce the risk of irritation to your oesophagus, you should carefully follow the dosage instructions:

- Take your alendronate immediately after getting up for the day, not at bedtime. (If you are taking alendronate for osteoporosis, you will only need to take the tablet one day each week).
- Swallow the tablet whole with a full glass of plain water only. Mineral water and other drinks, such as fruit juices, coffee and tea, may reduce its absorption.
- Stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing the tablet. Do not eat, or drink anything except plain water during this time. You should also not take antacids or calcium supplements for at least 30 minutes as these could reduce the absorption of alendronate.
- Do not chew or suck the tablet, as this may cause mouth ulcers.
- Stay upright until after you have eaten your first food of the day.

Jaw bone problems

To help reduce the risk of jaw problems, such as infections and poor healing:

- Tell your doctor straight away if you notice any jaw pain or numbness, exposed bone, a bad mouth odour, slow healing (e.g. dental work does not heal properly), loose teeth or sore spots around dentures.
 - Let your doctor know if you need to have any dental procedures, including tooth extractions. You may want to review your dental health and have any dental work performed before commencing alendronate.
 - Look after your teeth by brushing and flossing regularly, avoiding too many sweet snacks. If you have dentures, make sure they are properly fitted and leave them out when possible (or to use soft liners to prevent sores).
 - Tell your dentist you are taking alendronate.
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7.
What else you should know about this medicine

Read the Consumer Medicine Information (CMI) leaflet.

Before you start taking a new medicine, you should read the CMI. The CMI will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (drug interactions)
- how to take the medicine
- the most possible side effects
- the ingredients.

You can get the CMI for Alendronate from:

- your doctor or pharmacist
- www.nps.org.au/consumers (click on 'Consumer Medicine Information' in the Quicklinks column on the left of the screen)
- Merck, Sharp and Dohme, the makers of Fosamax Once Weekly and Fosamax Plus – phone 1800 645 712 (free call within Australia), or Arrow Pharmaceuticals, the makers of Alendro Once Weekly – phone (03) 9839 2830. (The CMI may also be in the box for Alendro Once Weekly).

CMI's are available for most prescription medicines.

8.
Who can be prescribed this medicine on the PBS?

People with osteoporosis, who have suffered a fracture due to minimal trauma (e.g. no apparent injury or a minor injury such as a fall from a standing height or less), have been able to obtain alendronate (taken as a once-weekly tablet) on the Pharmaceutical Benefit Scheme (PBS) for several years.

On 1 April 2007, PBS eligibility for alendronate was extended to include people with osteoporosis who have not yet had a fracture but are at high risk of having one. To qualify, you must meet both of the following conditions:

- be aged 70 years and over*.
- have a bone mineral density (BMD) T-score of minus 3.0 or worse.

* For a medicine to be listed on the PBS it must be shown to be cost-effective. Whilst younger people with osteoporosis may also have a very low BMD, people over 70 years have an overall higher risk of fracture. The same benefits for reducing fracture risk have not been so clearly shown in people less than 70. Therefore alendronate is cost-effective and of most benefit to this older age group.

To coincide with changes to the PBS, on 1st April 2007, Medicare cover for bone mineral density scans was extended to include all people aged 70 years and older.

If you are eligible to receive alendronate under the PBS, you will need to pay an amount towards the cost of each prescription.

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For a complete list of possible side effects, see the consumer medicine information (CMI).

Talk to your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

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8. Who can be prescribed this medicine on the PBS?

At time of publication, the patient contribution for each prescription was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

Fosamax Once Weekly attracts a Brand Price Premium of 72c, which means that the cost for Fosamax Once Weekly will be:

- \$32.02 for people without a concession card
- \$5.72 for concession card holders

For people who receive concessional rates, the cost to the Government for each prescription is \$41.99 for Fosamax Once Weekly and \$41.27 for other brands of alendronate (once-weekly). For those who do not receive concessional rates for their prescriptions, the cost to the Government is \$15.69 for Fosamax Once Weekly and \$14.97 for other brands of alendronate (once-weekly).

9. Other ways to help this condition

Even if you are taking medicines for osteoporosis, there are other things you can do to help reduce your chance of fractures.

Osteoporosis Australia recommends that you:

Include enough calcium in your diet

Calcium is necessary for healthy bones. Three servings of dairy products a day (e.g. one serve = 250 mL milk, or 200 g tub of yoghurt, or 40 g cheddar cheese) will generally provide you with the recommended calcium intake. If your diet does not include enough calcium your doctor may recommend that you take calcium supplements.

Get enough vitamin D

Vitamin D is formed in the skin from sunlight exposure and plays an important role in increasing calcium absorption from foods. Ideally, you should get exposure to direct sunlight for 5–15 minutes, four to six times a week. However, avoid the hours of 10am–3pm, to reduce your risk of skin cancer. If you have dark skin, wear covered clothing, or are confined indoors for any reason your doctor may need to prescribe you a vitamin D supplement.

Get regular, appropriate exercise

Regular exercise can help to maintain bone health and reduce your risk of falls. People with osteoporosis should undertake exercise that improves muscle strength and balance (e.g. Tai Chi) to help prevent falls (see 'attend a falls prevention program or clinic'). Avoid vigorous weight-bearing exercise or other physical activities that could cause a fall or fracture. If you have osteoporosis, you should first consult your doctor or physiotherapist before starting an exercise program. The exercise program should be carefully adjusted to suit your age and overall health, including bone health.

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For more information, contact Osteoporosis Australia on 1800 242 141 (free call in Australia) or visit www.osteoporosis.org.au

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9. Other ways to help this condition

Attend a falls prevention program or clinic

Poor leg muscle strength, poor balance and poor eyesight can increase your risk of having a fall. Even a minor fall can lead to a fracture in someone with osteoporosis. Ask your doctor if there are any fall prevention clinics in your area. Strength and balance exercise have been shown to reduce the risk of falling. You may need to discuss with your doctor reducing some of your other medications, particularly if you are taking sedatives or medications to help you sleep. (These medications have been shown to increase your risk of falling). Osteoporosis Australia offers many ideas on how to prevent falls, including tips on how to reduce fall hazards in the home.

Quit smoking if you are a smoker and drink alcohol in moderation

If you smoke and/or drink excessive amounts of alcohol, you have a higher risk of fractures.

With alcohol, for example, it can make you drowsy and increase your chances of having a fall which can cause a fracture, especially if you are older.

10. How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine. (Note that alendronate is not a new drug. It has been used for at least 10 years for treating osteoporosis. However some of its rare side effects, such as problems in the jaw bone, have only recently been found).

All medicines go through four types of tests for their effectiveness, side effects and safety:

- Laboratory tests (not involving people)
- Phase 1 clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- Phase 2 clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- Phase 3 clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine's effectiveness and find out more about its side effects.

The Therapeutic Goods Administration (Australia's regulatory agency for medicines) checks these results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the PBS if they are shown to be as good or better than other available medicines for the same condition.

Why Medicine Update?

Medicine Update lets you know about new drugs and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than for older medicines. Its important to understand what evidence is available about both benefits and harms. Medicine Update provides balanced information to help you decide if a medicine is right for you.

Who wrote Medicine Update?

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals.

Who is it for?

Medicine Update is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

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Visit the NPS website to find out about our free activities and resources
for consumers www.nps.org.au/consumers



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