

ALENDRO ONCE WEEKLY

alendronate sodium monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALENDRO ONCE WEEKLY.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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

What ALENDRO ONCE WEEKLY are used for

ALENDRO ONCE WEEKLY is used to treat osteoporosis in men and postmenopausal women.

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.

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.

ALENDRO ONCE WEEKLY belongs to a group of medicines called bisphosphonates.

ALENDRO ONCE WEEKLY works by slowing down the process of old bone being removed, which allows the bone forming cells time to rebuild normal bone.

ALENDRO ONCE WEEKLY not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, it reverses the progression of osteoporosis. Although it starts working on the bone cells immediately, measurable effects on bone mass may not be seen for several months or more.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why ALENDRO ONCE WEEKLY has been prescribed for you.

ALENDRO ONCE WEEKLY is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take ALENDRO ONCE WEEKLY if you are allergic to:

- alendronate sodium
- any of the ingredients listed at the end of this leaflet.

Do not take ALENDRO ONCE WEEKLY if you:

- have certain disorders of the food pipe (also called oesophagus), including those that cause difficulty swallowing
- are unable to stand or sit upright for at least 30 minutes
- have low levels of calcium in your blood.

Do not take ALENDRO ONCE WEEKLY if you are pregnant or breastfeeding.

It has not been studied in pregnant or breastfeeding women, so it is not known whether taking it can affect your baby.

Do not take your medicine if the expiry date (Exp.) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take it if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or to breastfeed.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems
- swallowing or digestive problems, such as ulcers.

Tell your doctor if you are planning to have any dental procedures or dental surgery.

If you know that you need to have any dental work performed, make sure that you discuss

this with your doctor as they may decide it is best to delay the commencement of ALENDRO ONCE WEEKLY until the work has been completed.

If you have not told your doctor about any of the above, tell them before you start taking ALENDRO ONCE WEEKLY.

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.

Some medicines may affect the way other medicines work.

Some medicines are likely to interfere with the absorption of ALENDRO ONCE WEEKLY if taken at the same time. These include:

- antacids
- calcium supplements
- vitamins.

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

You can take aspirin while you are being treated with this medicine. However, both aspirin and ALENDRO ONCE WEEKLY can increase the chance of a stomach upset.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicine to be careful with or avoid while taking ALENDRO ONCE WEEKLY.

How to take it

How much to take

Take ALENDRO ONCE WEEKLY only when prescribed by your doctor.

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

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

Follow all directions given to you by your doctor and pharmacist carefully.

When and how to take it

Take ALENDRO ONCE WEEKLY after getting up for the day and before taking your first food, beverage, or other medication.

Do not take it at bedtime.

Swallow ALENDRO ONCE WEEKLY whole with a full glass of plain water.

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

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

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

Do not chew or suck on a tablet of ALENDRO ONCE WEEKLY.

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 ALENDRO ONCE WEEKLY for as long as your doctor prescribes. ALENDRO ONCE WEEKLY 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.

If you forget to take it

If you forget to take ALENDRO ONCE WEEKLY, take your next dose the following morning.

If you take the forgotten tablet after you have eaten or had a drink, ALENDRO ONCE WEEKLY will not work as well as it should. Therefore, it is better to skip the dose that you missed.

Do not take two tablets on the same day to make up for the dose that you missed. 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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ALENDRO ONCE WEEKLY. 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. Do not induce vomiting. Do not lie down.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ALENDRO ONCE WEEKLY.

Tell all the doctors, dentists, oral or facial surgeons and pharmacists who are treating you that you are taking ALENDRO ONCE WEEKLY.

It 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.

Ensure that you maintain good oral hygiene while you are taking ALENDRO

ONCE WEEKLY, especially following any dental procedure.

If you become pregnant while taking ALENDRO ONCE WEEKLY, stop taking the tablets and tell your doctor.

If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking ALENDRO ONCE WEEKLY and tell your doctor.

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.

Things you must not do

Do not use ALENDRO ONCE WEEKLY to treat any other conditions unless your doctor tells you to.

Do not give ALENDRO ONCE WEEKLY to anyone else, even if they have the same condition as 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 ALENDRO ONCE WEEKLY.

Like all other medicines, this one may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer 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, vomiting
- constipation, diarrhoea
- headache
- aching muscles, joints or bones

- flu-like symptoms, typically at the start of treatment, such as aching muscles, generally feeling unwell or fever.

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 of the eyes
 - jaw pain and/or toothache
 - symptoms of low blood calcium levels including muscle cramps or spasms, or tingling sensation in the fingers or around the mouth
 - jaw problems, associated with delayed healing and infection, often following a tooth extraction or dental procedure.
- If jaw problems develop, tell your dentist as well as your doctor.**

If any of the following happen, stop taking ALENDRO ONCE WEEKLY 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.

If any of the following happen, stop taking ALENDRO ONCE WEEKLY and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- 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
- black tar-like and/or bloody stools.

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

After using it

Storage

Keep ALENDRO ONCE WEEKLY 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.

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ALENDRO ONCE WEEKLY or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

ALENDRO ONCE WEEKLY comes as a white to off-white, oval tablet marked 'AN 70' on one side.

Each blister pack contains 4 tablets.

Ingredients

The active ingredient in ALENDRO ONCE WEEKLY is alendronate sodium.

Each ALENDRO ONCE WEEKLY tablet contains 70 mg of alendronate sodium.

The tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- lactose monohydrate
- magnesium stearate.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
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Australian registration number:

ALENDRO ONCE WEEKLY – AUST R
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