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

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

What is in this leaflet

This leaflet answers some common questions about ALENDRONATE-GA. It is particularly important that you read the sections “When to take it” and “How to take it” before you take this medicine. The leaflet 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 ALENDRONATE-GA against the benefits they expect it will have for you.

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

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

What ALENDRONATE-GA is used for

ALENDRONATE-GA is used to treat osteoporosis. It is also used to treat or prevent osteoporosis in people who are receiving corticosteroid medicines, such as prednisone and dexamethasone.

In addition, ALENDRONATE-GA is used to prevent osteoporosis in postmenopausal women who have low bone mass.

These conditions are caused by changes in the way bone is normally maintained.

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.

Before you start to take it

Tell your doctor if you:

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

A dental examination should be considered before you start treatment with ALENDRONATE-GA. It is especially important if you have any of the conditions listed below:

- Cancer
- Undergoing chemotherapy or radiotherapy
- Taking steroids
- Don't receive routine dental care
- Have gum disease
- Suffer from anaemia
- Have 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 ALENDRONATE-GA.

Your doctor may decide to discontinue ALENDRONATE-GA treatment if you are scheduled for oral surgery.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your 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 ALENDRONATE-GA 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, Sinecort, Titralite
- calcium supplements
- vitamins

Therefore, take ALENDRONATE-GA 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 ALENDRONATE-GA. However, both aspirin and ALENDRONATE-GA may increase the chance of stomach upsets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ALENDRONATE-GA.
How to take ALENDRONATE-GA

How much to take
Take ALENDRONATE-GA only when prescribed by your doctor.

For the treatment and prevention of osteoporosis, the usual dose is one 70 mg tablet once a week.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this 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 ALENDRONATE-GA 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 Alendronate -GA 70 mg on the same day of the week every week.

Swallow ALENDRONATE-GA whole with a full glass of plain water only.

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

Stay upright for at least 30 minutes after swallowing ALENDRONATE-GA 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).

ALENDRONATE-GA 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-GA by interfering with its absorption into the body.

Do not chew or suck on a tablet of ALENDRONATE-GA.

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 ALENDRONATE-GA for as long as your doctor prescribes. ALENDRONATE-GA 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 weekend or over holidays.

If you forget to take it
Skip the dose you missed and take your next dose the following morning.

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose 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 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 ALENDRONATE-GA. 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 using ALENDRONATE-GA

Things you must do
Take ALENDRONATE-GA 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 ALENDRONATE-GA and call your doctor.

Visit you doctor regularly for check ups.

If you become pregnant while taking ALENDRONATE-GA, stop taking the tablets and tell your doctor.

If you are about to be started on any new medicine tell your doctor, pharmacist or dentist who is treating you that you are taking ALENDRONATE-GA.

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

If you need a laboratory investigation such as blood or urin 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.

Things you must not do
Do not give ALENDRONATE-GA to anyone else, even if they have the same condition as you.

Do not use ALENDRONATE-GA to treat other complaints unless your doctor tells you to.

Do not stop taking ALENDRONATE-GA or change the dosage without checking with your doctor.

Be careful driving or operating machinery until you know how ALENDRONATE-GA 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 ALENDRONATE-GA

ALENDRONATE-GA 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 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 (nausea), vomiting
- constipation, diarrhoea
- headache
- aching muscles, joints or bones
- flu-like symptoms, 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 ALENDRONATE-GA. For the most part, these have been mild.

Tell your doctor or dentist 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
- swelling or pain in the jaw with/ without infections of the gums/ teeth that take a long time to heal. ALENDRONATE-GA 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 onto the jaw

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

If any of the following happen, stop taking ALENDRONATE-GA 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.
If any of the following happen, stop taking ALENDRONATE-GA and tell your doctor immediately or go to the emergency department at your 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 nettlerash
- black tar-like and/or bloody stools

These may be serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

If you have the swelling described above, you may be having a serious allergic reaction to ALENDRONATE-GA

Rarely, stomach or duodenal ulcers (some severe) and uncommon episodes of irregular heartbeat have occurred, but it is not known whether these were caused by ALENDRONATE-GA.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

ALENDRONATE-GA is not addictive.

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After using ALENDRONATE-GA

**Storage**

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Keep ALENDRONATE-GA in a cool dry place where the temperature 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 or on window sills. Heat and dampness can destroy some medicines

Keep it 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 tells you to stop taking ALENDRONATE-GA tablets or you find they have passed their expiry date, ask your pharmacist what to do with any that are left over.

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**Product description**

**What ALENDRONATE-GA looks like?**

Alendronate-GA 70 mg tablets 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:**

Magnesium stearate, Mannitol, Croscarmellose sodium, Purified Talc, Colloidal Anhydrous Silica.

**Supplier**

ALENDRONATE-GA tablets are supplied in Australia by:

Ascent Pharma Pty Ltd
151-153 Clarendon Street
South Melbourne VIC 3205

Australian Registration Number : AUST R 150495

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