

Alendronate Sandoz®

Alendronate sodium 70 mg tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Alendronate Sandoz. It is particularly important that you read the section "When and how to take it" before you take this medicine. This 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 risk of you taking this medicine against the benefits it is expected to 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 SANDOZ IS USED FOR

Alendronate Sandoz is used to treat osteoporosis including osteoporosis caused by a group of medicines known as corticosteroids.

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.

How Alendronate Sandoz works

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

Alendronate Sandoz contains the active ingredient alendronate sodium and belongs to a group of non-hormonal medicines called bisphosphonates.

There is no evidence that this medicine is addictive.

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

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE ALENDRONATE SANDOZ

You should know that Alendronate Sandoz can irritate or burn the food pipe (also called oesophagus) in some people. The chances of this happening should be reduced if you follow the precautions and instructions for taking Alendronate Sandoz.

When you must not take it

Do not take this medicine if:

- you are allergic to alendronate sodium or any of the inactive ingredients listed at the end of this leaflet under Product Description
- you have certain disorders of the food pipe 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
- your dentist advises you to; always consult your doctor first.

Do not give this medicine to a child.

Safety and effectiveness in children has not been established.

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

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as Alendronate Sandoz
- any other substances, including foods, preservatives or dyes.

Tell your doctor if you plan on becoming pregnant or will be breastfeeding while you are taking Alendronate Sandoz.

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

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

Tell your doctor if you are planning to have a course of dental surgery.

If you have not told your doctor about any of the above, tell him/her before you start taking Alendronate Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines are likely to interfere with the absorption of Alendronate Sandoz 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[®], Mucaïne[®], Mylanta[®], Rennie[®], Salvital[®], Simeco[®], Titalac[®]
- calcium supplements
- vitamins.

Therefore, take Alendronate Sandoz 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 Sandoz. However both aspirin and Alendronate Sandoz may increase the chance of stomach upsets.

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

HOW TO TAKE ALENDRONATE SANDOZ

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.

How much to take

Take Alendronate Sandoz only when prescribed by your doctor.

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

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

When and how to take it

Take Alendronate Sandoz after getting up for the day. Do not take it at bedtime.

Swallow one tablet with a full glass of plain water.

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

Stay upright for at least 30 minutes after swallowing Alendronate Sandoz 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 Sandoz 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 Sandoz by interfering with its absorption into the body.

Do not chew or suck on a tablet of Alendronate Sandoz.

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

How long to take Alendronate Sandoz

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

Alendronate Sandoz can only 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 miss a tablet, take one tablet 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 about what to do, talk to your doctor or pharmacist.

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

If you take too much (overdose)

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

WHILE YOU ARE TAKING ALENDRONATE SANDOZ

Things you must do

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

If you become pregnant while taking this medicine, 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 Alendronate Sandoz.

If you require a dental procedure, tell your dentist that you are taking Alendronate Sandoz.

If you develop new or unusual pain in your hip or thigh, tell your doctor.

Rarely, patients have experienced fracture in a specific part of the thigh bone.

If you break a bone (have a fracture), tell your doctor that you are taking Alendronate Sandoz.

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 give your medicine to anyone else, even if they have the same condition as you.

Do not take Alendronate Sandoz to treat any other complaint unless your doctor tells you to.

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 Sandoz.

Alendronate Sandoz 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist 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 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 joints
- dizziness or spinning sensation
- unusual tiredness or weakness
- swelling of hands, ankles or feet
- hair loss.

Most of these are the common side effects of the medicine. 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
- new or unusual pain in the hip or thigh
- jaw problems, associated with delayed healing and infection, often following a tooth extraction.

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

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

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

The above list includes very 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 Sandoz.

Rare cases of stomach and duodenal ulcers (some severe) have occurred in some people, but it is not known whether these were caused by Alendronate Sandoz.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Alendronate Sandoz 70 mg tablets:
AUST R 285166 (blister)

Trademarks

AFTER TAKING ALENDRONATE SANDOZ

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 your medicine in a cool dry place where the temperature stays below 25°C. Do not freeze the product.

Do not store Alendronate Sandoz or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill. 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 this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Alendronate Sandoz 70 mg tablets: white, round with "ALN 70" marked on one side. Available in blisters of 4 tablets.

Ingredients

Active Ingredient:

Alendronate Sandoz 70 mg tablet - contains 70 mg of alendronic acid as alendronate sodium.

Inactive Ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- Film coat consists of (microcrystalline cellulose, carrageenan, macrogol 8000).

This medicine does not contain any lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Alendronate Sandoz is supplied in Australia by:

Sandoz Pty Ltd.
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

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