

APO-Alendronate Plus D3 Tablets

Contains the active ingredient alendronate acid (as alendronate sodium) and colecalciferol (vitamin D3)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Alendronate Plus D3. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Alendronate Plus D3 tablets. It contains the active ingredient alendronate sodium and colecalciferol (vitamin D3).

It is used to:

- treat osteoporosis
- provide additional vitamin D

Osteoporosis is caused by changes in the way bone is normally maintained. Vitamin D is an essential nutrient required for calcium absorption and healthy bones.

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.

What should I know about vitamin D?

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. Clothing or sun block can prevent enough sunlight from getting through. In addition, as people age, their skin becomes less able to make vitamin D. Very few foods are natural sources of vitamin D.

Too little vitamin D leads to inadequate calcium absorption and low phosphate-minerals that make bones strong. Even if you are eating a diet rich in calcium or taking a calcium supplement, your body cannot absorb calcium properly unless you have enough vitamin D. Too little vitamin D may lead to bone loss and osteoporosis. Severe vitamin D deficiency may cause muscle weakness which can lead to falls and a higher risk of fracture.

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

This medicine is available only with a doctor's prescription.

How it works

The alendronate in this medicine works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. Alendronate not only helps prevent the loss of bone but actually helps to rebuild bone and make bone less likely to fracture. Thus, Alendronate Plus D3 reverses the progression of osteoporosis.

Alendronate Plus D3 starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

The alendronate in this medicine belongs to a group of non-hormonal medicines called bisphosphonates.

In addition to alendronate, Alendronate Plus D3 also contains vitamin D3, an essential nutrient required for calcium absorption and healthy bones.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

You should know that in some people, Alendronate Plus D3 can irritate or burn the food pipe (also called oesophagus). The chances of this

happening should be reduced when you follow the instructions for 'How to take this medicine' in this leaflet.

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - You have certain disorders of the food pipe (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.
- **You are hypersensitive to, or have had an allergic reaction to, Alendronate, vitamin D or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - swallowing or digestive problems, such as ulcers
 - dental or jaw-bone problems or are planning to have a course of dental surgery
3. You currently smoke or have been a smoker in the past
4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
5. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines are likely to interfere with the absorption of Alendronate Plus D3. These include:

- antacids, medicines used to treat indigestion
- calcium supplements

- vitamins

Therefore, take this medicine 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 any of these.

Other medicines not listed above may also interact with Alendronate Plus D3. If you are taking any of these you may need a different dose or you may need to take different medicines. Your doctor has more information on medicines to be careful with or avoid while taking Alendronate Plus D3.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

The usual dose of Alendronate Plus D3 is one tablet once a week.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow one tablet whole with a full glass of plain water.

Do not take any food, medicines or drinks other than plain tap water with this medicine.

It is important to take Alendronate Plus D3 with plain water only, not mineral water. Food, other drugs and mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of this medicine by interfering with the absorption into the body.

Stay upright for at least 30 minutes after swallowing Alendronate Plus D3 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).

Do not chew or suck on a tablet of Alendronate Plus D3.

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

When to take it

Take Alendronate Plus D3 after getting up for the day. Do not take it at bedtime.

Choose the day of the week that best fits your schedule. Every week, take one tablet of Alendronate Plus D3 on your chosen day.

Alendronate Plus D3 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 Plus D3 by interfering with its absorption into the body.

How long to take it for

It is important that you continue taking Alendronate Plus D3 for as long as your doctor prescribes.

Alendronate Plus D3 can only treat your osteoporosis, by helping prevent further loss of

bone and continuing to rebuild bone, if you take it every week.

Make sure you have enough to last over weekends and holidays.

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 to make up for missed doses. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you have trouble remembering to take your medicine, ask your doctor for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn
- you develop a toothache or require a dental procedure
- you develop new or unusual pain in your leg Rarely, patients have experienced fracture in a specific part of the thigh bone.
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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 this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

There have been side effects reported with this medicine that may affect your ability to drive or operate machinery. Individual responses to this medicine may vary (see Possible side effects).

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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
- changed sense of taste

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 your hip or thigh

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- jaw-bone or dental problems (including toothache). Jaw-bone problems may include infection, and delayed healing after a tooth extraction or other work that involves drilling into the jaw-bone
- 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 you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to Alendronate Plus D3, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Alendronate Plus D3 tablets look like

70 mg/70 mcg tablets:

White to off-white biconvex, oval shaped tablet. Engraved "APO" on one side, "A-D28" on the other side.

Blister Pack of 4

70 mg/140 mcg tablets:

White to off-white, rectangular, biconvex tablet. Engraved "APO" on one side, "ALE-D56" on the other side.

Blister Pack of 4

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 70 mg alendronate acid (as alendronate sodium) and 70 mcg or 140 mcg colecalciferol (vitamin D3) as the active ingredients.

It also contains the following inactive ingredients:

- mannitol
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- butylated hydroxytoluene.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Alendronate Plus D3 70 mg/70 mcg tablet (blister pack): AUST R 220372.

APO-Alendronate Plus D3 70 mg/140 mcg tablet (blister pack): AUST R 220376.

Sponsor

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