

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

This leaflet answers some common questions about this medicine. It 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 this medicine 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 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).

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

It is used to:

- treat osteoporosis
- provide additional vitamin D

Osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

Osteoporosis is caused by changes in the way bone is normally maintained.

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.

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.

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 helps to rebuild bone and make bone less likely to fracture.

Vitamin D is an essential nutrient required for calcium absorption and healthy bones. 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. Low vitamin D levels

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.

There is no evidence that this medicine is addictive.

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 an allergy to:

- any medicine containing alendronate or vitamin D
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if:

- 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

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

Alendronate and colecalciferol (vitamin D3) in this medicine may pass into breast milk and there is a possibility that your baby may be affected.

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 it has expired or is damaged, return it to your pharmacist for disposal.

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, foods, preservatives or dyes.

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

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

- dental or jaw-bone problems or are planning to have a course of dental surgery

Tell your doctor if you currently smoke or have been a smoker in the past.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 Plus D3. These include:

- antacids, used to treat indigestion
- calcium supplements
- vitamins

These medicines may be affected by Alendronate Plus D3 or may affect how well it works.

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.

You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take this medicine

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

They may differ from the information contained in this leaflet.

How much to take

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

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, 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

Continue taking your medicine for as long as your doctor tells you.

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.

It is important to keep taking your medicine even if you feel well.

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.

This may increase the chance of you getting an unwanted side effect.

Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you are not sure what to do, ask 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 the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. 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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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 take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

There have been side effects reported with this medicine that may affect your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious but 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.

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 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 as soon as possible 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

- discomfort or pressure of the ears, including possible discharge
- new or unusual pain in your hip or thigh
- 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.

- 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

The above list includes serious side effects that may require medical attention.

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

- symptoms of an allergic reaction including 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
- black tar-like and/or bloody stools

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Alendronate Plus D3 APOTEX tablets looks like

70mg/70mcg tablets:

White to off-white biconvex, oval shaped tablet. Engraved "APO" on one side, "A-D28" on the other side. AUST R 220372.

Blister Pack of 4

70mg/140 mcg tablets:

White to off-white, rectangular, biconvex tablet. Engraved "APO" on one side, "ALE-D56" on the other side. AUST R 220376

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.

Sponsor

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