

ALENDRONATE PLUS D3 APOTEX

Alendronate sodium and colecalciferol

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 095 055

What is in this leaflet

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

All medicines have risks and benefits. Your doctor will have 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

Alendronate Plus D3 APOTEX contains both alendronate and colecalciferol (vitamin D). It is used to treat osteoporosis and to provide additional vitamin D.

Alendronate belongs to a group of medicines called bisphosphonates. Vitamin D is an essential nutrient required for calcium absorption and healthy bones.

Understanding bone

Throughout life, old bone is being broken down and rebuilt as 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 age 35 this balance is disturbed, with bone loss occurring at a slightly faster rate than it can be replaced. After menopause, hormonal changes in women cause bone loss at an even faster rate. Excessive bone loss causes bones to become thinner and weaker, and therefore more likely to break.

Osteoporosis

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 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 osteoporosis usually has

no symptoms. However, if left untreated it can result in broken bones or fractures. Spinal bone fractures may go unnoticed until they cause height loss. Fractures may occur during everyday activities, 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 to pain, deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

What should I know about vitamin D?

The main source of vitamin D is through exposure to the sun, 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. Vitamin D deficiency may cause bone loss, osteoporosis and muscle weakness, which can lead to falls and a higher risk of fracture.

How it works

Alendronate works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. This reverses the progression of osteoporosis by helping to prevent the loss of bone, rebuild bone and make bone less likely to fracture. Alendronate starts

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

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

You doctor may have prescribed it for another reason.

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- alendronate
- colecalciferol (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.

Alendronate can irritate or burn the food pipe (oesophagus). The chances of this happening should be reduced when you follow the instructions in this leaflet.

Do not take this medicine if you are unable to stand or sit upright for at least 30 minutes.

Do not take this medicine if your doctor has told you that you currently have low blood calcium.

Do not take this medicine if your dentist advises you to consult your doctor first.

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

This medicine has not been studied in pregnant or breastfeeding 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 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 any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have kidney disease or swallowing or digestive problems, such as ulcers.

Tell your doctor if you have dental or jaw-bone problems or are planning to have dental surgery.

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

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

Taking other medicines

Tell your doctor and 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 may interfere with the absorption of alendronate if taken at the same time. These include:

- antacids, used to treat indigestion e.g. Gaviscon, Mylanta
- calcium supplements or vitamins

Therefore, this medicine should be taken at least 30 minutes before taking any of the above medicines.

You can take aspirin while you are taking this medicine, however, this combination may increase the risk of stomach upsets.

These medicines may be affected by this medicine or may affect how well it works. 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 to 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

The usual dose is one tablet taken once a week on the same day each week. Choose the day of the week that best fits your schedule.

How to take it

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

Stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing the tablet and until after you have eaten your first food of the day.

Do not lie down immediately after swallowing it.

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

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 the tablet.

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

When to take it

Take this medicine once a week on the same day each week.

This medicine should be taken after getting up for the day. Do not take it at bedtime.

This medicine should be taken on empty stomach. Food, drinks (other than plain water), and other medicines will

lessen the effect of this medicine 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.

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. Return to taking one tablet once a week on your original chosen day.

Do not take two tablets on the same 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 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 once:

- drink a full glass of milk
- do not induce vomiting
- do not lie down

While you are using this medicine

Things you must do

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

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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

If you develop a toothache or require a dental procedure, tell your dentist that you are taking this medicine.

Tell your doctor if you develop new or unusual pain in your leg.

Rarely, patients have experienced fracture in the thigh bone.

Make sure you have an adequate intake of calcium in your diet.

Your doctor, dietician or pharmacist can suggest suitable foods to eat.

Things you must not do

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

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first discussing it with your doctor.

Things to be careful of

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

Things that may be helpful for your osteoporosis

Talk to your doctor or pharmacist about the self-help measures suggested below for more information:

- Regular exercise can be helpful in building and maintaining strong bones, such as a brisk walk.

- Eat a balanced diet. Your doctor may advise to increase the amount of calcium in your diet by eating calcium-rich foods or taking a calcium supplement.
- 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 or reduce smoking.
- Your doctor may advise you to reduce the amount of alcohol you drink. Drinking excessively on a regular basis may increase the risk of osteoporosis.

Side effects

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

This medicine 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 attention 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 or pharmacist if you notice any of the following and they worry you:

- stomach complaints, such as pain, wind, feeling sick, vomiting, constipation, diarrhoea
- an uncomfortable feeling in the stomach or belching after eating (dyspepsia or heartburn)
- headache
- aching muscles, joints or bones
- flu-like symptoms at the start of treatment, such as aching muscles, feeling unwell and fever
- joint swelling, swelling of hands, ankles or feet
- dizziness or spinning sensation, unusual tiredness or weakness
- hair loss
- changed sense of taste

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- skin rash, redness of the skin, sometimes made worse by sunlight, itchiness
- mouth ulcers
- blurred vision, eye pain or redness

- muscle cramps or spasms, tingling sensation in the fingers or around the mouth (low blood calcium levels)
- new or unusual pain in your hip or thigh
- stomach or duodenal ulcers
- pinkish, itchy swellings on the skin (hives or nettle rash)
- jaw-bone or dental problems, including toothache, infection, and delayed healing after a tooth extraction or other work that involves drilling into the jawbone

The above list includes rare 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:

- difficulty or pain upon swallowing, new or worsening heartburn, chest pain
- severe skin reactions
- 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 (signs of an allergic reaction)
- black, tar-like bloody stools

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

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

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

Storage and Disposal

Storage

Keep your medicine in the pack until it is time to take it. Protect from light and moisture.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays 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, light 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 it looks like

70 mg/70 microgram tablets: White to off- white, modified capsule shaped uncoated tablet, debossed with 'ADC' on one side and '28' on the other side. AUST R 308732.

70 mg/140 microgram tables: white to off- white, modified capsule shaped uncoated tablet, debossed with 'ADC' on one side and '56' on the other side. AUST R 308733.

Available in blister packs of 1 and 4 tablets.

*Not all strengths and pack types may be available.

Ingredients

Each tablet contains 70 mg of alendronate sodium and either 70 or 140 micrograms of colecalciferol as the active ingredients.

It also contains the following:

- microcrystalline cellulose

- medium chain triglycerides
- gelatin
- croscarmellose sodium
- sucrose
- colloidal anhydrous silica
- magnesium stearate
- butylated hydroxytoluene
- povidone

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

Sponsor

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