

## Fosamax Plus D-Cal™

Alendronate sodium/colecalciferol and calcium carbonate

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about FOSAMAX PLUS D-Cal. It is particularly important that you read the sections "When to take it" 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 risks of you taking FOSAMAX PLUS D-Cal 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 FOSAMAX PLUS D-Cal is used for

FOSAMAX PLUS D-Cal is a combination medicine consisting of 4 once weekly tablets of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) together with 48 tablets of BoneCal®.

FOSAMAX PLUS D-Cal is used to treat osteoporosis and to provide additional vitamin D and additional calcium.

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. Calcium is an essential mineral, necessary to maintain the bone structure in the body.

#### Understanding bone

Bone is a 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. This balanced process keeps your skeleton healthy and strong. 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.

#### What should I know about calcium?

Calcium is vital for healthy teeth and bones and also plays a crucial role in other systems of the body, such as the health and functioning of nerves and muscle tissue. People at different life stages need different amounts of calcium - young children, teenagers and older men and women all have greater than average requirements. Many Australian adults do not achieve the recommended amount of calcium in their diets and can benefit from calcium supplements.

Not having enough calcium in your diet may lead to disorders like osteoporosis. Making sure you have enough calcium in your diet is an important way to slow bone loss and keep bones strong. If not enough calcium from food and supplements can be absorbed to keep blood calcium normal, the body will remove calcium from the bones. If your dietary intake of calcium is constantly low, your body will eventually remove so much calcium from the skeleton that your bones will become weak and brittle and more likely to break.

#### How does FOSAMAX PLUS D-Cal work?

The alendronate in FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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, FOSAMAX PLUS 70mg/140 micrograms (5600 IU) reverses the progression of osteoporosis. FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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 FOSAMAX PLUS 70mg/140 micrograms (5600 IU) belongs to a group of non-hormonal medicines called bisphosphonates.

In addition to alendronate, FOSAMAX PLUS 70mg/140 micrograms (5600 IU) also contains

vitamin D, an essential nutrient required for calcium absorption and healthy bones.

BoneCal contains calcium, an essential mineral necessary to help maintain the bone structure in the body.

#### Before you take FOSAMAX PLUS D-Cal

You should know that in some people, FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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 FOSAMAX PLUS D-Cal' in this leaflet.

#### When you must not take it

**Do not take FOSAMAX PLUS 70mg/140 micrograms (5600 IU) if:**

- you have an allergy to FOSAMAX PLUS 70mg/140 micrograms (5600 IU) or any of the ingredients listed at the end of this leaflet
- 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
- your dentist advises you to consult your doctor first

**Do not take BoneCal if:**

- your doctor has told you that you currently have high blood calcium
- you have kidney stone
- you have an allergy to BoneCal or any of the ingredients listed at the end of this leaflet.

**Do not take FOSAMAX PLUS D-Cal if you are pregnant or breast-feeding.**

FOSAMAX Plus D-Cal has not been studied in pregnant or breast-feeding women.

**Do not take FOSAMAX PLUS D-Cal if:**

- the packaging is damaged or shows signs of tampering
- the expiry date on the blister pack has passed. If you take this medicine after the expiry date has passed, it may not work.

**If you are not sure whether you should start taking FOSAMAX PLUS D-Cal, talk to your doctor.**

**Do not give FOSAMAX PLUS D-Cal to a child.**

FOSAMAX PLUS D-Cal has not been studied in children.

#### Before you start to take it

**Tell your doctor if:**

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

4. you have dental or jaw-bone problems or are planning to have a course of dental surgery
5. you currently 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 any FOSAMAX PLUS D-Cal.

### **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 FOSAMAX PLUS 70mg/140 micrograms (5600 IU) if taken at the same time. These include:

- antacids, medicines used to treat indigestion e.g. Gaviscon, Mylanta
- calcium supplements such as BoneCal (as provided in this pack of FOSAMAX PLUS D-Cal) or Caltrate
- vitamins

Therefore, take FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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 medicines.

You can take aspirin while you are being treated with FOSAMAX PLUS D-Cal. However, both aspirin and FOSAMAX PLUS 70mg/140 micrograms (5600 IU) may increase the chance of stomach upsets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking FOSAMAX PLUS D-Cal.

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## **How to take FOSAMAX PLUS D-Cal**

### **How much to take**

Take FOSAMAX PLUS D-Cal only when prescribed by your doctor.

#### **DAY 1**

**FOSAMAX PLUS 70mg/140 micrograms (5600 IU) (white tablet in the blister pack)**

The usual dose of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) is one tablet once a week.

Choose the day of the week that best fits your schedule. Every week, take one tablet of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) on your chosen day (DAY 1).

Do not take BoneCal tablets on DAY 1.

#### **DAYS 2-7**

**BoneCal (pale green tablets supplied in the bottle)**

The usual dose of BoneCal is one or two tablets daily, as recommended by your doctor. On the day after you have taken your FOSAMAX PLUS 70mg/140 micrograms (5600 IU) tablet, take one or two BoneCal tablets. Continue taking these every day for a total of 6 days. 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**

**DAY 1: FOSAMAX PLUS 70mg/140 micrograms (5600 IU)**

Take FOSAMAX PLUS 70mg/140 micrograms (5600 IU) after getting up for the day and before taking your first food, beverage or other medication. Do not take it at bedtime.

Do not take BoneCal tablets on DAY 1.

Swallow one tablet whole with a full glass of plain water [not mineral water, not coffee or tea, not juice].

Do not take any food, medicines or drinks other than plain tap water with your FOSAMAX PLUS 70mg/140 micrograms (5600 IU).

It is important to take FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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 FOSAMAX PLUS 70mg/140 micrograms (5600 IU) by interfering with the absorption into the body.

Stay upright for at least 30 minutes after swallowing FOSAMAX PLUS 70mg/140 micrograms (5600 IU) 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).

FOSAMAX PLUS 70mg/140 micrograms (5600 IU) is effective only if taken when your stomach is empty. Food, drinks other than plain water, and other medicines will lessen the effect of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) by interfering with its absorption into the body.

Do not chew or suck on a tablet of FOSAMAX PLUS 70mg/140 micrograms (5600 IU).

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

#### **DAYS 2 to 7: BoneCal**

Take one or two BoneCal tablets, as recommended by your doctor, for 6 days, starting the day after you have taken your FOSAMAX PLUS 70mg/140 micrograms (5600 IU) tablet.

BoneCal may be taken before or with food.

**THIS SEVEN DAY CYCLE IS TO BE REPEATED EACH WEEK.**

### **How long to take it**

It is important that you take FOSAMAX PLUS D-Cal for as long as your doctor prescribes it. FOSAMAX PLUS D-Cal can only treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it as directed. Since it is not known how long you should take FOSAMAX PLUS D-Cal, you should discuss the need to stay on this medication with your doctor periodically to determine if FOSAMAX PLUS D-Cal is still right for you.

### **If you forget to take it**

**FOSAMAX PLUS 70mg/140 micrograms (5600 IU):**

If you miss a tablet, take one tablet on the morning after you remember.

Do not take two tablets on the same day. Do not take your FOSAMAX PLUS 70mg/140 micrograms (5600 IU) at the same time you

take your BoneCal tablet. Return to taking one tablet of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) once a week, as originally scheduled on your chosen day (DAY 1) followed by one or two tablets of BoneCal on days 2 to 7, and then repeat the cycle.

### **BoneCal:**

If you forget to take your BoneCal dose, then just skip that dose and continue taking your tablets on the day that you remember. Do not take more than your daily dose on any given day.

Do not take your FOSAMAX PLUS 70mg/140 micrograms (5600 IU) at the same time you take your BoneCal tablets.

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 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 a large number of tablets. 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.

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## **While you are using FOSAMAX PLUS D-Cal**

### **Things you must do**

If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAMAX PLUS D-Cal and call your doctor.

If you become pregnant while taking FOSAMAX PLUS D-Cal, 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 FOSAMAX PLUS D-Cal.

If you develop a toothache or require a dental procedure, tell your dentist that you are taking FOSAMAX PLUS D-Cal.

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

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

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 FOSAMAX PLUS D-Cal to anyone else, even if they have the same condition as you.

### **Things to be careful of**

There have been side effects reported with FOSAMAX PLUS D-Cal that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX PLUS D-Cal may vary (see Side Effects).

### **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 like BoneCal. 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.

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## Side Effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FOSAMAX PLUS D-Cal.**

FOSAMAX PLUS D-Cal 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 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

Most of these are the more common side effects of FOSAMAX PLUS D-Cal. 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
- ear pain
- 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
- symptoms of a kidney stone such as severe, lower back or abdominal pain or difficulty in passing urine. If you have a kidney stone, your dose of BoneCal may need to be reduced or discontinued.

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

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

- 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.

These side effects are rare and may be serious.

**If any of the following happen, stop taking FOSAMAX PLUS D-Cal 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 FOSAMAX PLUS D-Cal 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 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

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

If you have the swelling described above, you may be having a serious allergic reaction to FOSAMAX PLUS D-Cal.

Rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by FOSAMAX PLUS D-Cal.

**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. FOSAMAX PLUS D-Cal is not addictive.

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## After using FOSAMAX PLUS D-Cal

### Storage

**Keep your tablets in the original containers (blister pack and bottle) until it is time to take them.**

If you take the tablets out of the original containers they may not keep well.

**Keep FOSAMAX PLUS D-Cal in a cool dry place where the temperature stays below 30°C. Do not freeze the product. Keep the tablets away from light or moisture. Do not store FOSAMAX PLUS D-Cal 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 FOSAMAX PLUS D-Cal, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product Description

### What it looks like

FOSAMAX PLUS D-Cal is a combination pack consisting of a box of 4 once weekly tablets of FOSAMAX PLUS 70mg/140 micrograms (5600 IU) together with a bottle of 48 tablets of BoneCal.

FOSAMAX PLUS 70mg/140 micrograms (5600 IU): comes as a white to off-white, modified rectangle-shaped tablet with "270" on one side and a bone image on the other.

BoneCal comes as a pale green, capsule shaped tablet.

### Ingredients

**FOSAMAX PLUS 70mg/140 micrograms (5600 IU) contains the active ingredients:**

- alendronate sodium equivalent to 70 mg alendronic acid per tablet
- colecalciferol 140 micrograms (5600 IU vitamin D3) per tablet

Inactive ingredients:

- cellulose-microcrystalline
- lactose anhydrous
- medium chain triglycerides
- gelatin
- croscarmellose sodium
- sucrose
- silica-colloidal anhydrous
- magnesium stearate
- butylated hydroxytoluene
- modified food starch
- aluminium sodium silicate.

FOSAMAX PLUS 70mg/140 micrograms (5600 IU) does not contain gluten, tartrazine or any other azo dyes.

BoneCal contains 1250mg calcium carbonate equivalent to 500mg elemental calcium per tablet.

Inactive ingredients:

- cellulose-microcrystalline
- maltodextrin
- acacia
- crospovidone
- hypromellose
- titanium dioxide
- magnesium stearate
- macrogol 400
- carnauba wax
- iron oxide yellow CI77492
- chlorophyllin copper complex

BoneCal does not contain gluten or preservatives.

### Supplier

FOSAMAX PLUS D-Cal is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited Level 1, Building A, 26 Talavera Road, Macquarie Park NSW 2113

BoneCal is supplied in Australia by:

Vitaco Health Australia Pty Ltd Level 1, 82 Waterloo Road, North Ryde, NSW 2113

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### Australian Register Numbers:

FOSAMAX PLUS D-Cal

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