

# FOSAMAX<sup>®</sup> PLUS Once Weekly

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using FOSAMAX PLUS?

FOSAMAX PLUS contains the active ingredients alendronate sodium and colecalciferol. FOSAMAX PLUS is used to treat osteoporosis and to provide additional vitamin D.

For more information, see Section [1. Why am I using FOSAMAX PLUS?](#) in the full CMI.

### 2. What should I know before I use FOSAMAX PLUS?

Do not use if you have ever had an allergic reaction to FOSAMAX PLUS or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use FOSAMAX PLUS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FOSAMAX PLUS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FOSAMAX PLUS?

- The usual dose of FOSAMAX PLUS is one tablet once a week.
- It is important to take FOSAMAX PLUS with plain water only, stay upright for at least 30 minutes after swallowing FOSAMAX PLUS and do not take any food, medicines or drinks other than plain tap water during this time.

More instructions can be found in Section [4. How do I use FOSAMAX PLUS?](#) in the full CMI.

### 5. What should I know while using FOSAMAX PLUS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using FOSAMAX PLUS.</li><li>• Stop taking FOSAMAX PLUS and tell your doctor if you develop difficulty or pain when swallowing, chest pain, new or worsening heartburn, new or unusual pain in your hip, leg or other bone.</li><li>• Make sure you have an adequate intake of calcium in your diet.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give FOSAMAX PLUS to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• There have been side effects reported with FOSAMAX PLUS that may affect your ability to drive or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Your doctor may advise you to cut down on the amount of alcohol you drink.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep FOSAMAX PLUS in a cool, dry place where the temperature stays below 30°C.</li><li>• Keep the tablets away from light or moisture, and do not remove them from the blister until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while using FOSAMAX PLUS?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include stomach pain, gas in the stomach or bowel, wind, heartburn, nausea, vomiting, constipation, diarrhoea, muscle or joint pain and headache.

Serious side effects include allergic reactions, severe skin reactions, jaw bone or dental problems, pain or difficulty when swallowing, worsening heartburn, chest pain, new or unusual pain in your hip or thigh.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FOSAMAX PLUS Once Weekly

Active ingredient(s): *Alendronate sodium/colecalciferol*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FOSAMAX PLUS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FOSAMAX PLUS.**

Where to find information in this leaflet:

- [1. Why am I using FOSAMAX PLUS?](#)
- [2. What should I know before I use FOSAMAX PLUS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FOSAMAX PLUS?](#)
- [5. What should I know while using FOSAMAX PLUS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking FOSAMAX PLUS?

**FOSAMAX PLUS contains the active ingredients alendronate sodium and colecalciferol (Vitamin D3).** The alendronate in FOSAMAX PLUS belongs to a group of non-hormonal medicines called bisphosphonates.

In addition to alendronate, FOSAMAX PLUS also contains vitamin D, an essential nutrient required for calcium absorption and healthy bones.

**FOSAMAX PLUS is used to treat osteoporosis and to 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 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.

### **How does FOSAMAX PLUS work?**

The alendronate in FOSAMAX PLUS 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 reverses the progression of osteoporosis.

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

## 2. What should I know before I take FOSAMAX PLUS?

### Warnings

#### Do not use FOSAMAX PLUS if:

- you are allergic to alendronate sodium, colecalciferol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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
- you are pregnant or breast-feeding.
- the packaging is torn or shows signs of tampering

#### Check with your doctor if you:

- have any other medical conditions especially kidney disease, or swallowing or digestive problems, such as ulcers
- take any medicines for any other condition
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- have dental or jaw-bone problems or are planning to have a course of dental surgery.
- you currently smoke or have been a smoker in the past.

#### Irritation of the food pipe (oesophagus)

You should know that in some people, FOSAMAX PLUS can irritate or burn the food pipe (also called oesophagus). The chances of this happening should be reduced when you follow the instructions in section 4. How do I take FOSAMAX PLUS?

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

FOSAMAX PLUS has not been studied in pregnant or breast-feeding women.

#### Use in children

Do not give FOSAMAX PLUS to a child.

FOSAMAX PLUS has not been studied in children.

## 3. What if I am taking other medicines?

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

- **Some medicines are likely to interfere with the absorption of FOSAMAX PLUS if taken at the same time. These include:** antacids, medicines used to treat indigestion e.g. Gaviscon, Mylanta
- calcium supplements
- vitamins

Therefore, take FOSAMAX PLUS at least 30 minutes before taking any of these or other medicines to make sure there is no problem with absorption.

You can take aspirin while you are being treated with FOSAMAX PLUS. However, both aspirin and FOSAMAX PLUS may increase the chance of stomach upsets.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FOSAMAX PLUS.**

## 4. How do I take FOSAMAX PLUS?

### How much to take

- Take FOSAMAX PLUS only when prescribed by your doctor.
- The usual dose of FOSAMAX PLUS is one tablet once a week.
- Follow the instructions provided and use FOSAMAX PLUS until your doctor tells you to stop.
- It is important that you take FOSAMAX PLUS for as long as your doctor prescribes it. FOSAMAX PLUS can only treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it every week. Since it is not known how long you should take FOSAMAX PLUS, you should discuss the need to stay on this medication with your doctor periodically to determine if FOSAMAX PLUS is still right for you.

### When to take FOSAMAX PLUS

- Choose the day of the week that best fits your schedule. Every week, take one tablet of FOSAMAX PLUS on your chosen day.
- Take FOSAMAX PLUS after getting up for the day and before taking your first food, beverage or other medication. Do not take it at bedtime.

### How to take FOSAMAX PLUS

- 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.
- It is important to take FOSAMAX PLUS 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 by interfering with the absorption into the body.

- **Stay upright for at least 30 minutes after swallowing FOSAMAX PLUS 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 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 by interfering with its absorption into the body.
- **Do not chew or suck on a tablet of FOSAMAX PLUS.** Mouth ulcers may occur if the tablet is chewed or dissolved in the mouth.

### **If you forget to take FOSAMAX PLUS**

FOSAMAX PLUS should be used regularly at the same time each week. 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 FOSAMAX PLUS, ask your pharmacist for some hints.

### **If you take too much FOSAMAX PLUS**

If you take too many tablets at one time, drink a full glass of milk. Do not induce vomiting. Do not lie down.

#### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking FOSAMAX PLUS?**

### **Things you should do**

**Stop taking FOSAMAX PLUS and call your doctor straight away if you:**

- develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn

- become pregnant while taking FOSAMAX PLUS [include relevant statements about monitoring of the condition and relevant action(s) to be taken]
- [include relevant statement(s) about action to be taken if the condition worsens / does not improve]

Remind any doctor, dentist or pharmacist you visit that you are using FOSAMAX PLUS.

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

If you develop new or unusual pain in your hip, leg or other bone, tell your doctor. Rarely, patients have experienced fracture in a specific part of the thigh bone. Patients have experienced fractures in other bones as well.

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 should not do**

- Do not give FOSAMAX PLUS to anyone else, even if they have the same condition as you.

### **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.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how FOSAMAX PLUS affects you.**

There have been side effects reported with FOSAMAX PLUS that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX PLUS may vary

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

If you drink alcohol excessively on a regular basis you may increase your risk of developing osteoporosis. Your doctor may advise you to cut down the amount of alcohol you drink.

### **Looking after your medicine**

- Keep FOSAMAX PLUS in a cool dry place where the temperature stays below 30°C.

- Do not freeze the product. 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• stomach pain, gas in the stomach or bowel, wind</li> <li>• an uncomfortable feeling in the stomach or belching after eating, also called dyspepsia, or heartburn</li> <li>• feeling sick (nausea), vomiting</li> <li>• constipation, diarrhoea</li> </ul> <p><b>Head and nervous system-related:</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness or spinning sensation</li> <li>• changed sense of taste</li> </ul> <p><b>Muscle/skeleton-related:</b></p> <ul style="list-style-type: none"> <li>• aching muscles, joints and/or bones, which rarely can be severe</li> <li>• swelling of joints</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• hair loss</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<p><b>General conditions:</b></p> <ul style="list-style-type: none"> <li>• flu-like symptoms typically at the start of treatment, such as aching muscles, generally feeling unwell and rarely fever</li> <li>• unusual tiredness or weakness</li> <li>• swelling of hands, ankles or feet</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• skin rash or redness of the skin, sometimes made worse by sunlight, itchiness</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• mouth ulcers</li> </ul> <p><b>Eye/ear-related:</b></p> <ul style="list-style-type: none"> <li>• blurred vision, pain or redness in the eye</li> <li>• ear pain</li> </ul> <p><b>Muscle/skeleton-related:</b></p> <ul style="list-style-type: none"> <li>• new or unusual pain in your hip or thigh</li> </ul> <p><b>General conditions:</b></p> <ul style="list-style-type: none"> <li>• symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth</li> </ul>	<p><b>Tell your doctor immediately if you notice any of these serious side effects.</b></p> <p><b>These side effects are rare, and very rarely, may be serious.</b></p>
<p><b>Muscle/skeleton-related:</b></p> <ul style="list-style-type: none"> <li>• Jaw-bone or dental problems (including toothache).</li> </ul> <p>Jaw-bone problems may include infection, and delayed healing after a tooth extraction or other work that involves drilling into the jaw-bone.</p>	<p><b>Tell your dentist and doctor immediately if you notice this serious side effect.</b></p>

Serious side effects	What to do
<p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>difficulty or pain upon swallowing</li> <li>chest pain</li> <li>new or worsening heartburn</li> </ul> <p>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.</p>	<p><b>Stop taking FOSAMAX PLUS and tell your doctor immediately if you experience these serious side effects.</b></p>
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing</li> <li>pinkish, itchy swellings on the skin, also called hives or nettlerash</li> </ul> <p>If you have the swelling described above, you may be having a serious allergic reaction to FOSAMAX PLUS.</p> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>severe skin reactions</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>black tar-like and/or bloody stools</li> <li>Rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by FOSAMAX PLUS.</li> </ul>	<p><b>Stop taking FOSAMAX PLUS, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What FOSAMAX PLUS contains

<b>Active ingredients</b>	alendronate sodium colecalfiferol
<b>Other ingredients</b>	microcrystalline cellulose lactose medium chain triglycerides gelatin croscarmellose sodium sucrose colloidal anhydrous silica magnesium stearate dry vitamin D3 100 purified water butylated hydroxytoluene modified food starch aluminium sodium silicate.
<b>Potential allergens</b>	FOSAMAX PLUS contains lactose.  FOSAMAX PLUS does not contain gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What FOSAMAX PLUS looks like

FOSAMAX PLUS comes in two strengths of tablets, each containing 70mg alendronate but with different strengths of colecalciferol (vitamin D3), either 70 micrograms (2800 IU) or 140 micrograms (5600 IU):

FOSAMAX PLUS (70mg/70 micrograms) comes as a white to off-white, modified capsule-shaped tablet with the outline of a bone image on one side and "710" on the other. (Aust R 113482.).

FOSAMAX PLUS 70mg/140 micrograms: comes as a white to off-white, modified-rectangle shaped tablet with "270" on one side and a bone image on the other. (AUST R 136846).

A box of tablets contains 4 tablets (trade pack).

### Who distributes FOSAMAX PLUS

Organon Pharma Pty Ltd  
Level 5, 66 King St  
Sydney NSW 2000  
Australia

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