

## **FOSAMAX PLUS™ 70/70**

*alendronate sodium/colecalciferol*

70 mg/70 mcg tablet (No longer available in New Zealand)

## **FOSAMAX PLUS™ 70/140**

*alendronate sodium/colecalciferol*

70 mg/140 mcg tablet

### **What is in this leaflet**

This leaflet answers some common questions about FOSAMAX PLUS. It is particularly important that you read the sections “When to take it” and “How to take it” before you take this medicine. The 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 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 is used for**

FOSAMAX PLUS is used for the treatment of osteoporosis in select patients where vitamin D supplementation is recommended.

### **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 and also may occur in men. Osteoporosis often occurs in women several years after, the menopause, which 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). The earlier a woman reaches the menopause, the greater the risk of osteoporosis. Osteoporosis can also occur in men due to several causes, including ageing and/or a lower level of male hormone testosterone. In all instances, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. Therefore, maintaining bone mass and preventing further bone loss are important to keep your skeleton healthy.

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.

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

#### Alendronate

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 makes 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.

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.

#### Vitamin D

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 - the 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 greater risk of fracture.

### **Before you take FOSAMAX PLUS**

You should know that FOSAMAX PLUS can irritate or burn the food pipe in some people. The chances of this happening should be reduced if you follow the precautions and instructions for taking FOSAMAX PLUS.

#### **When you must not take it**

Do not take FOSAMAX PLUS if:

- you have an allergy to FOSAMAX PLUS or any of the ingredients listed at the end of this leaflet
- you have certain disorders of the food pipe (also called 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 FOSAMAX PLUS if you are pregnant or breast-feeding. FOSAMAX PLUS has not been studied in pregnant or breast-feeding women.

Do not take FOSAMAX PLUS if:

- the packaging is torn or shows signs of tampering

- the expiry date on the 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, talk to your doctor.

Do not give FOSAMAX PLUS to a child. FOSAMAX PLUS has not been studied in children.

### **Before you start to take it**

Tell your doctor if:

- you plan to become pregnant or breast-feed
- you have any dental problems
- you have any medical conditions, especially the following:
  - kidney disease
  - swallowing or digestive problems, such as ulcers
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have lactose intolerance
- you are or have been a smoker.

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

### **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 if taken at the same time. These include:

- antacids, such as Aludrox\*, Aludrox Plus\*, Amphojel\*, Andrews Effervescent\*, Eno\* powder, Gavisgon\*, Mylanta\*, Quickeze\*, Roter\*, Titalac\*, Titalac-Sil\*, Tums\*, Ural\*
- 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. Check with your doctor or pharmacist if you are not sure whether you are taking an antacid.

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.

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

### **Effects on the Ability to Drive and Use Machinery**

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. (See Adverse Effects.)

## **How to take FOSAMAX PLUS**

### **How much to take**

Take FOSAMAX PLUS only when prescribed by your doctor.

For osteoporosis in men and in postmenopausal women, the usual dose is one 70 mg/70 mcg tablet or one 70 mg/140 mcg once a week.

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**

1. Choose the day of the week that best fits your schedule. Every week take one FOSAMAX PLUS tablet on your chosen day.
2. 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.
3. Swallow FOSAMAX PLUS whole with a full glass of plain water only. It is important to take FOSAMAX PLUS with plain water only, not mineral water. 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.
4. Stay upright for at least 30 minutes after swallowing FOSAMAX PLUS. Do not lie down immediately after swallowing it. It is important to stay upright, for example, 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).
5. Wait at least 30 minutes before taking any food, other drinks or medicines. 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.
6. 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.

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

It is important that you continue taking FOSAMAX PLUS for as long as your doctor prescribes. FOSAMAX PLUS can only treat your osteoporosis by helping prevent further loss of bone and continuing to rebuild bone and to help make sure you get enough vitamin D, if you take it every week.

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

Take just one FOSAMAX PLUS 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 take the forgotten tablet after you have eaten or had a drink, FOSAMAX PLUS will not work as well as it should. Therefore, it is better to skip the dose that you missed.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

### **If you take too much (overdose)**

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FOSAMAX PLUS. 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.

## **While you are using FOSAMAX PLUS**

### **Things you must do**

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

If you become pregnant while taking FOSAMAX PLUS, 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.

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.

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.

### **Things you must 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.
- 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.

## **Adverse Effects**

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

FOSAMAX PLUS helps most people with osteoporosis, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse 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
- bone, muscle and/or joint pain which is rarely severe (most patients experienced relief after stopping the medicine)
- transient flu-like symptoms (rarely with fever), typically at the start of treatment
- hair loss
- a changed sense of taste

These are the more common adverse effects of FOSAMAX PLUS. 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
- itching
- mouth ulcers
- eye pain
- severe skin reactions
- jaw problems associated with delayed healing and infection (often following tooth extraction)
- joint swelling or swelling in hands or legs
- dizziness
- unusual tiredness or weakness
- new or unusual pain in the hip or thigh

These adverse effects are rare and very rarely may be serious.

### **If any of the following happen, stop taking FOSAMAX PLUS and tell your doctor immediately:**

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

These adverse effects may be due to irritation or ulceration of the food pipe. They may worsen if you continue taking the tablets. Rarely, these adverse effects may be serious.

### **If any of the following happen, stop taking FOSAMAX PLUS 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 nettlerash
- black-tar-like and or bloody stools

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

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

Rarely, stomach or duodenal ulcers (some severe) have occurred.

Other adverse 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 adverse effects. You may not experience any of them.

FOSAMAX PLUS is not addictive.

## **After using FOSAMAX PLUS**

### **Storage**

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.

Store your tablets at 20-25°C. Occasional storage up to 30°C is allowed. Protect from moisture and light. Do not store it 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 the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

## **Product description**

### **Availability**

FOSAMAX PLUS 70 mg/70 mcg is no longer available in New Zealand. Only FOSAMAX PLUS 70 mg/140 mcg is available.

### **What FOSAMAX PLUS looks like**

FOSAMAX PLUS (alendronate sodium/colecalciferol) is a tablet that contains the active ingredients:

- 70 mg alendronate, and 70 mcg of colecalciferol (2800 IU of vitamin D<sub>3</sub>),  
or
- 70 mg alendronate, and 140 mcg of colecalciferol (5600 IU of vitamin D<sub>3</sub>)

FOSAMAX PLUS 70 mg/70 mcg comes as a white to off-white, modified capsule-shaped tablet with an outline of a bone image on one side and 710 on the other.

A box contains four 70 mg/70 mcg tablets. (No longer available in New Zealand.)

FOSAMAX PLUS 70 mg/140 mcg comes as a white to off-white modified rectangle shaped tablet with an outline of a bone image on one side and 270 on the other.

A box contains four 70 mg/140 mcg tablets.

## **Ingredients**

### Active ingredients:

- alendronate monosodium salt trihydrate
- colecalciferol

### Inactive ingredients:

- microcrystalline cellulose
- lactose anhydrous
- croscarmellose sodium
- magnesium stearate
- medium chain triglycerides
- gelatine
- sucrose
- colloidal silicon dioxide
- butylated hydroxytoluene
- modified food starch (maize)
- sodium aluminum silicate

FOSAMAX PLUS does not contain gluten, tartrazine or any other azo dyes.

## **Supplier**

FOSAMAX PLUS is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited  
P O Box 99 851  
Newmarket  
Auckland  
NEW ZEALAND  
Tel: 0800 500 673

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\* Trade name