

FOSAMAX[®] PLUS

Alendronate Sodium/Cholecalciferol (70mg/5600I.U.)

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What FOSAMAX PLUS is used for

Your doctor has prescribed FOSAMAX PLUS to treat your osteoporosis and to help make sure you get enough vitamin D. This will help prevent you from developing fractures.

How is normal bone maintained?

Bone undergoes a normal process of rebuilding that occurs continuously throughout your skeleton. First, old bone is removed (resorbed), then new bone is laid down (formed). This balanced process of resorbing and forming bone keeps your skeleton healthy and strong.

What is osteoporosis and why should it be treated?

Osteoporosis is thinning and weakening of the bones. It is common in women after menopause and may also occur in men. Osteoporosis often occurs in women several years after the menopause, which occurs when the ovaries stop producing the female hormone, estrogen, 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 aging and/or a low level of the 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. If left untreated, however, it can result in fractures (broken bones). 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 of Vitamin D is through exposure to summer sunlight, which makes vitamin D in our skin. Clothing or sun block can prevent from getting enough sunlight. 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, and severe vitamin D deficiency may cause muscle weakness which can lead to falls, and greater risk of fracture.

How can osteoporosis be treated?

Your doctor has prescribed FOSAMAX PLUS to treat your osteoporosis and to help make sure you get enough vitamin D. FOSAMAX PLUS not only prevents the loss of bone but actually helps to rebuild bone you may have lost and makes bone less likely to fracture. Thus, FOSAMAX PLUS reverses the progression of osteoporosis.

In addition, your doctor may recommend one or more of the following lifestyle changes:

Stop smoking. Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture.

Exercise. Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise program.

Eat a balanced diet. Your doctor can advise you whether to modify your diet or to take any dietary supplements.

Why is it important to continue to take FOSAMAX PLUS?

It is important to take FOSAMAX PLUS over the long term to continue to prevent loss of bone, to help rebuild bone you may have lost and to help make sure you get enough vitamin D. It is, therefore, important to follow your doctor's instructions when taking FOSAMAX PLUS

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without skipping doses or varying from your prescribed treatment schedule.

How FOSAMAX PLUS works

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

- 70mg alendronate and 140mcg of cholecalciferol (5600 IU of vitamin D₃)

FOSAMAX PLUS provides a week's worth of vitamin D.

The alendronate in FOSAMAX PLUS is a member of a class of non-hormonal drugs called bisphosphonates. FOSAMAX PLUS helps to rebuild bone and makes bone less likely to fracture. Vitamin D is an essential nutrient, required for calcium absorption and healthy bones.

In osteoporosis FOSAMAX PLUS works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. FOSAMAX PLUS 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.

Before you use FOSAMAX PLUS

-When you must not use it

Do not take FOSAMAX PLUS if you:

- Have certain disorders of the esophagus (the tube that

connects your mouth with your stomach)

- Are unable to stand or sit upright for at least 30 minutes
- Are allergic to any of its ingredients (see section **Product Description**)
- Your doctor has told you that you currently have low blood calcium

-Before you start to use it

Tell your doctor or pharmacist about any medical or dental problems you have or have had, including known kidney disease, about any allergies and if you are or have been a smoker. If you have any swallowing or digestive problems, discuss them with your doctor before taking FOSAMAX PLUS.

Use in pregnancy and breast feeding

Do not take FOSAMAX PLUS if you are pregnant or breast feeding.

Use in children

FOSAMAX PLUS is not indicated for use in children.

Use in elderly

FOSAMAX PLUS works equally well in and is equally well tolerated by patients older and younger than 65 years of age.

-Taking other medicines

You should always tell your doctor about all drugs you are taking or plan to take, including those obtained without a prescription, particularly the followings:

- any hormone or glucocorticoid medicines
- nonsteroidal anti-inflammatory drugs (NSAID)

Some medicines are likely to interfere with the absorption of

FOSAMAX PLUS if taken at the same time (See in *When to use it*).

How to use FOSAMAX PLUS

-How much to use

One 70 mg/5600 IU tablet once weekly

-When to use it

Choose the day of the week that best fits your schedule. Every week, take one FOSAMAX PLUS tablet on your chosen day.

After getting up for the day and before taking your first food, beverage, or other medication, swallow your FOSAMAX PLUS tablet with a full glass (6-8 ounces or 180-240 mL) of plain water only.

Not Mineral water

Not Coffee or tea

Not Juice

Do not chew or suck on a tablet of FOSAMAX PLUS.

After swallowing your FOSAMAX PLUS tablet, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. FOSAMAX PLUS is effectively only if taken when your stomach is empty.

-How long to use it

It is important that you continue taking FOSAMAX PLUS for as long as your doctor prescribes it. 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.

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-If you forget to use it

If you miss a dose, just take 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 use too much (overdose)

If you take too many tablets, drink a full glass of milk and contact your doctor immediately. Do not induce vomiting. Do not lie down. If you take too many tablets, you may have an upset stomach, heartburn, throat or stomach irritation, and ulcer.

While you are using FOSAMAX PLUS

-Things you must do

After swallowing your FOSAMAX PLUS tablet do not lie down – stay fully upright (sitting, standing or walking) for at least 30 minutes and do not lie down until after your first food of the day.

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

-Things you must not do

Do not take FOSAMAX PLUS at bedtime or before getting up for the day.

The above actions will help the FOSAMAX PLUS tablet reach your stomach quickly and help reduce the potential for irritation of your esophagus (the tube that connects your mouth with your stomach).

-Things you must be careful of

Can I drive or operate machinery while using FOSAMAX PLUS?

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 “**Side effects**”)

Side effects

Most patients do not have side effects from FOSAMAX PLUS; however, as with any medicine, FOSAMAX PLUS may have unintended or undesirable effects.

- Side effects usually have been mild. Some patients may experience digestive disturbances such as nausea, vomiting, or black and/or bloody stools.
- Some digestive disturbances may be severe including irritation or ulceration of the esophagus (the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing.
- These reactions may occur especially if patients do not drink the recommended amount of water with FOSAMAX PLUS and/or if they lie down in less than 30 minutes or before their first food of the day. Esophageal reactions may worsen if patients continue to take FOSAMAX PLUS after developing symptoms suggesting irritation of the esophagus.
- Some patients may experience bone, muscle and/or joint pain which rarely is severe. Patients who develop severe bone, joint, and/or muscle pain should contact their physician. Most

patients experienced relief after stopping the drug.

- Rarely, patients may also experience joint swelling or swelling in their hands or legs.
- Transient flu-like symptoms (rarely with fever), typically at the start of treatment, have occurred.
- In rare cases, patients taking FOSAMAX PLUS may get itching or eye pain, ear pain or a rash that may be made worse by sunlight.
- Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear which can occur very rarely.
- Hair loss has been reported.
- Rarely, severe skin reactions may occur. Allergic reactions such as hives or, rarely, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing may occur.
- Patients may experience dizziness or a changed sense of taste.
- Rarely, stomach or other peptic ulcers (some severe) have occurred. Mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.
- Rarely, patients have had jaw problems associated with delayed healing and infection, often following tooth extraction.
- Rarely, patients have experienced fracture in a specific part of the thigh bone. Patients have experienced fractures in other bones as well. If you develop new or unusual pain in the hip, thigh or any other bone, contact your doctor.

Your doctor or pharmacist has a more complete list. Tell your

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doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF or vaccines (AEFI))]

Storage and Disposal of FOSAMAX PLUS

-Storage

Store FOSAMAX PLUS up to 30°C. Protect from moisture and light. Store tablets in the original blister package until use.

Keep FOSAMAX PLUS and all medicines safely away from children.

How long should I keep my medicine?

Do not use this medicine after the month and year shown by

the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

FOSAMAX PLUS 70 mg/5600 IU: White to off-white, modified rectangular shaped tablet with "270" on one side and an outline of a bone shape on the other side.

-Ingredients

-Active ingredients: *Alendronate Sodium and Cholecalciferol*

-Inactive ingredients: Lactose anhydrous, Microcrystalline

Cellulose, Colloidal Silicon Dioxide, Sodium, Magnesium Stearate.

-MAL number:

FOSAMAX PLUS 70 MG/5600 I.U. COMBINATION TABLET: MAL08031392ACRZ

Manufacturer

Rovi Pharma Industrial Services, S.A Via Complutense, 140 28805 Alcala de Henares Madrid Spain

Product Registration Holder

Organon Malaysia Sdn. Bhd. 3A-08-02, Level 8, Corporate Tower 3A, Pavilion Damansara Heights, No. 3, Jalan Damansara 50490 Kuala Lumpur, Malaysia.

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