

Patient Information

FOSAMAX PLUS D™ (FOSS-ah-max PLUS D) (alendronate sodium/cholecalciferol) Tablets

Read the patient information before you start taking FOSAMAX PLUS D*. Also, read the leaflet each time you refill your prescription, just in case anything has changed. This leaflet does not take the place of discussions with your doctor about your medical condition or treatment. You and your doctor should discuss FOSAMAX PLUS D when you start taking your medicine and at regular checkups.

What is the most important information I should know about FOSAMAX PLUS D?

- You must take FOSAMAX PLUS D exactly as directed to help make sure it works and to help lower the chance of harmful side effects.
- Choose the day of the week that best fits your schedule. Every week, take 1 FOSAMAX PLUS D tablet on your chosen day.
- After getting up for the day and before taking your first food, drink, or other medicine, swallow your FOSAMAX PLUS D tablet with a full glass (6-8 oz) of plain water only.

Do **not** take FOSAMAX PLUS D with:

Mineral water
Coffee or tea
Juice

- Do not chew or suck on a tablet of FOSAMAX PLUS D.
- After swallowing your FOSAMAX PLUS D tablet, do not lie down – stay fully upright (sitting, standing, or walking) for at least 30 minutes. Do not lie down until after your first food of the day. This will help the FOSAMAX PLUS D tablet reach your stomach quickly and help reduce the chance that FOSAMAX PLUS D might irritate your esophagus, the tube that connects your mouth with your stomach.
- After swallowing your FOSAMAX PLUS D tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium, and other supplements and vitamins. FOSAMAX PLUS D is effective only if it is taken when your stomach is empty.
- Do not take FOSAMAX PLUS D at bedtime or before getting up for the day.
- If you have chest pain, new or worsening heartburn, or have trouble or pain when you swallow, stop taking FOSAMAX PLUS D and call your doctor.

Some patients may need more vitamin D than is in FOSAMAX PLUS D. Your doctor may recommend additional vitamin D supplementation.

What is FOSAMAX PLUS D?

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FOSAMAX PLUS D is a prescription medicine that contains alendronate sodium and vitamin D₃ (cholecalciferol) as the active ingredients. FOSAMAX PLUS D provides a week's worth of vitamin D₃ (2800 IU). The Daily Value is 400 IU.

FOSAMAX PLUS D is used for:

- The treatment of osteoporosis (thinning of bone) in women after menopause. It reduces the chance of having a hip or spinal fracture (break).
- Treatment to increase bone mass in men with osteoporosis.

Improvement in bone density may be seen as early as 3 months after you start taking FOSAMAX PLUS D. For FOSAMAX PLUS D to continue to work, you need to keep taking it.

FOSAMAX PLUS D is not a hormone.

There is more information about osteoporosis and vitamin D at the end of this leaflet.

Who should not take FOSAMAX PLUS D?

Do not take FOSAMAX PLUS D if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Cannot stand or sit upright for at least 30 minutes
- Have low levels of calcium in your blood
- Have severe kidney disease
- Are allergic to FOSAMAX PLUS D or any of its ingredients. A list of ingredients is at the end of this leaflet.

If you are pregnant or nursing, talk to your doctor about whether taking FOSAMAX PLUS D is right for you based on possible risk to you and your child.

Talk to your doctor if you have or have had:

- Problems with swallowing
- Stomach or digestive problems
- Sarcoidosis, leukemia, lymphoma
- Other medical problems you have or had in the past

Also tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you see your doctor or get a new medicine.

How should I take FOSAMAX PLUS D?

See “What is the most important information I should know about FOSAMAX PLUS D?” for important information about how to take the medicine and to help make sure it works for you. In addition, follow these instructions:

- Take 1 dose of FOSAMAX PLUS D **once a week**.

- Choose the day of the week that best fits your schedule. Every week take 1 tablet of FOSAMAX PLUS D on your chosen day.
- After getting up for the day and before taking your first food, drink, or other medicine, swallow your FOSAMAX PLUS D tablet with a full glass (6-8 oz) of plain water only.
- It is important that you keep taking FOSAMAX PLUS D for as long as your doctor says to take it. For FOSAMAX PLUS D to continue to work, you need to keep taking it.
- If you miss a dose, take only 1 FOSAMAX PLUS D tablet on the morning after you remember. Do not take 2 tablets on the same day. Continue your usual schedule of 1 FOSAMAX PLUS D tablet once a week on your chosen day.
- If you think you took more than the prescribed dose of FOSAMAX PLUS D, drink a full glass of milk and contact your local poison control center or emergency room right away. Do not try to vomit. Do not lie down.

What should I avoid while taking FOSAMAX PLUS D?

- **Do not eat, drink, or take other medicines or supplements before taking FOSAMAX PLUS D.**
- **Wait for at least 30 minutes after taking FOSAMAX PLUS D to eat, drink, or take other medicines or supplements.**
- **Do not lie down for at least 30 minutes after taking FOSAMAX PLUS D. Do not lie down until after your first food of the day.**

What are the possible side effects of FOSAMAX PLUS D?

Some patients may get severe digestive reactions from FOSAMAX PLUS D. (See “What is the most important information I should know about FOSAMAX PLUS D?”.) These reactions include irritation, inflammation, or ulcers of the esophagus, which may sometimes bleed. This may occur especially if patients do not drink a full glass of water with FOSAMAX PLUS D or if they lie down in less than 30 minutes or before their first food of the day. Esophagus reactions may get worse if patients continue to take FOSAMAX PLUS D after developing symptoms of an irritated esophagus.

Stop taking FOSAMAX PLUS D and call your doctor right away if you get any of these signs of possible serious problems:

- Chest pain
- Heartburn
- Trouble or pain when swallowing

Side effects in patients taking FOSAMAX PLUS D usually have been mild. They generally have not caused patients to stop taking FOSAMAX PLUS D.

The most common side effect is abdominal (stomach area) pain. Less common side effects are nausea, vomiting, a full or bloated feeling in the stomach, constipation, diarrhea, black or bloody stools (bowel movements), gas, headache, a changed sense of taste, and bone, muscle, or joint pain.

Severe bone, joint, and/or muscle pain has been reported in patients taking, by mouth, bisphosphonate drugs that are used to treat osteoporosis (thin bones). However, such reports have been rare. This group of drugs includes FOSAMAX PLUS D. Most of the patients were postmenopausal women (women who had stopped having periods). Patients developed pain within one day to several months after starting the

drug. Most patients experienced relief after stopping the drug. Patients who develop severe bone, joint, and/or muscle pain after starting FOSAMAX PLUS D should contact their physician.

Transient flu-like symptoms (rarely with fever), typically at the start of treatment, have occurred.

In rare cases, patients taking FOSAMAX PLUS D may get itching or eye pain, or a rash that may be made worse by sunlight. Rarely, severe skin reactions may occur. Patients may get allergic reactions, such as hives or, in rare cases, swelling that can be of their face, lips, tongue, or throat, which may cause trouble in breathing or swallowing. Mouth ulcers (sores) may occur if the FOSAMAX PLUS D tablet is chewed or dissolved in the mouth.

Anytime you have a medical problem you think may be from FOSAMAX PLUS D, even if it is not listed above, talk to your doctor.

What should I know about osteoporosis?

Normally your bones are being rebuilt all the time. First, old bone is removed (resorbed). Then a similar amount of new bone is formed. This balanced process keeps your skeleton healthy and strong.

Osteoporosis is a thinning and weakening of the bones. It is common in women after menopause, and may also occur in men. In osteoporosis, bone is removed faster than it is formed, so overall bone mass is lost and bones become weaker. Therefore, keeping bone mass is important to keep your bones healthy. In both men and women, osteoporosis may also be caused by certain medicines called corticosteroids.

At first, osteoporosis usually has no symptoms, but it can cause fractures (broken bones). Fractures usually cause pain. Fractures of the bones of the spine may not be painful, but over time they can make you shorter. Eventually, your spine can curve and your body can become bent over. Fractures may happen during normal, everyday activity, such as lifting, or from minor injury that would normally not cause bones to break. Fractures most often occur at the hip, spine, or wrist. This can lead to pain, severe disability, or loss of ability to move around (mobility).

Who is at risk for osteoporosis?

Many things put people at risk of osteoporosis. The following people have a higher chance of getting osteoporosis:

- Women who are going through or who are past menopause
- Men who are elderly

People who:

- Are white (Caucasian) or oriental (Asian)
- Are thin
- Have family member with osteoporosis
- Do not get enough calcium or vitamin D
- Do not exercise
- Smoke
- Drink alcohol often
- Take bone thinning medicines (like prednisone or other corticosteroids) for a long time

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. Winter sunlight in most of the United States is too weak to produce vitamin D. Even in the summer, 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. Some foods, such as milk, some brands of orange juice and breakfast cereals are fortified with vitamin D.

Too little vitamin D leads to low calcium absorption and low phosphate. These are 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.

What can I do to help treat osteoporosis?

In addition to FOSAMAX PLUS D, your doctor may suggest one or more of the following lifestyle changes:

- **Stop smoking.** Smoking may increase your chance of getting osteoporosis.
- **Reduce the use of alcohol.** Too much alcohol may increase the chance of osteoporosis and injuries that can cause fractures.
- **Exercise regularly.** Like muscles, bones need exercise to stay strong and healthy. Exercise must be safe to prevent injuries, including fractures. Talk with your doctor before you begin any exercise program.
- **Eat a balanced diet.** Having enough calcium in your diet is important. Your doctor can advise you whether you need to change your diet or take any dietary supplements, such as calcium or additional vitamin D.

What are the ingredients in FOSAMAX PLUS D?

Active ingredients: alendronate sodium and cholecalciferol (vitamin D₃). FOSAMAX PLUS D provides a week's worth of vitamin D₃ (2800 IU). The Daily Value is 400 IU.

Inactive ingredients: cellulose, lactose, medium chain triglycerides, gelatin, croscarmellose sodium, sucrose, colloidal silicon dioxide, magnesium stearate, butylated hydroxytoluene, modified food starch, and sodium aluminum silicate.

How do I store FOSAMAX PLUS D?

- Store FOSAMAX PLUS D at 68 to 77°F (20 to 25°C). Protect from moisture and light. Store tablets in the original blister package or bottle and carton until time of use.
- Safely discard FOSAMAX PLUS D that is out-of-date or no longer needed.
- **Keep all FOSAMAX PLUS D and all medicines out of the reach of children.**

General information about using FOSAMAX PLUS D safely and effectively


Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. This medicine was prescribed for your particular condition. Alendronate in FOSAMAX PLUS D acts specifically on your bones. Do not use it for another condition or give it to others.

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This leaflet is a summary of information about FOSAMAX PLUS D. If you have any questions or concerns about FOSAMAX PLUS D or osteoporosis, talk to your doctor, pharmacist, or other health care provider. You can ask your doctor or pharmacist for information about FOSAMAX PLUS D written for health care providers. For more information, call 1-877-408-4699 (toll-free) or visit the following website: www.fosamaxplusd.com.

Rx only

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