

Patient Information FOSAMAX® (alendronate sodium) Tablets

Read this information before you start taking FOSAMAX* (FOSS-ah-max). 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. You and your doctor should discuss FOSAMAX when you start taking your medicine and at regular checkups.

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

- **You must take FOSAMAX exactly as directed to help make sure it works and to help lower the chance of harmful side effects.**
- **After getting up for the day and before taking your first food, drink, or other medicine, swallow your FOSAMAX tablet with a full glass (6-8 oz) of plain water only.**
 - **Not** mineral water
 - **Not** coffee or tea
 - **Not** juice
- **Do not chew or suck on a tablet of FOSAMAX.**
- **After swallowing your FOSAMAX 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 tablet reach your stomach quickly and help reduce the chance that FOSAMAX might irritate your esophagus, the tube that connects your mouth with your stomach.
- **After swallowing your FOSAMAX 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 is effective only if it is taken when your stomach is empty.
- **Do not take FOSAMAX 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 and call your doctor.**

What is FOSAMAX?

FOSAMAX is for:

- The treatment or prevention 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.
- The treatment of osteoporosis in either men or women receiving corticosteroid medicines (for example, prednisone).

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

FOSAMAX is not a hormone.

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

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Who should not take FOSAMAX?

Do not take FOSAMAX 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 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 is right for you based on possible risk to you and your child.

Talk to your doctor about any:

- Problems with swallowing
- Stomach or digestive problems
- Other medical problems you have or have had in the past
- Medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements

How should I take FOSAMAX?

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

- After getting up for the day and before taking your first food, drink, or other medicine, swallow your FOSAMAX tablet with a full glass (6-8 oz) of plain water only.
- Take 1 FOSAMAX tablet once a day, every day.
- It is important that you keep taking FOSAMAX for as long as your doctor says to take it. For FOSAMAX to continue to work, you need to keep taking it.
- If you miss a dose, do not take it later in the day. Continue your usual schedule of 1 tablet once a day the next morning.
- If you think you took more than the prescribed dose of FOSAMAX, 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?

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

What are the possible side effects of FOSAMAX?

Some patients may get severe digestive reactions from FOSAMAX. (See “What is the most important information I should know about FOSAMAX?”) 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 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 after developing symptoms of an irritated esophagus.

Stop taking FOSAMAX 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 usually have been mild. They generally have not caused patients to stop taking FOSAMAX.

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, and/or joint pain.

Severe bone, joint, and/or muscle pain has been reported in patients taking, by mouth, bisphosphonates drugs that are used to treat osteoporosis (thin bones). However, such reports have been rare. This group of drugs includes FOSAMAX. 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 should contact their physician. 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 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. Patients may experience dizziness. Mouth ulcers (sores) may occur if FOSAMAX is chewed or dissolved in the mouth.

Rarely, patients have had jaw problems associated with delayed healing and infection, often following tooth extraction.

Anytime you have a medical problem you think may be from FOSAMAX, 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 can I do to help prevent or treat osteoporosis?

In addition to FOSAMAX, 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 risk 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 vitamin D.

What are the ingredients in FOSAMAX?

FOSAMAX contains alendronate sodium as the active ingredient and the following inactive ingredients: cellulose, lactose, croscarmellose sodium and magnesium stearate. The 10 mg tablet also contains carnauba wax.

How do I store FOSAMAX?

Store FOSAMAX at room temperature, 59-86°F (15-30°C).

Discard all expired medicines. Keep all medicines out of the reach of children.

General information about using FOSAMAX 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. FOSAMAX acts specifically on your bones. Do not use it for another condition or give it to others.

FOSAMAX is not indicated for use in children.

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

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