

1 Daily Use]

APPROVED
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Comments/Proposals

FOSAMAX® (Alendronate Sodium Tablets)

Patient Information about

FOSAMAX® (FOSS-ah-max) for Osteoporosis

Generic name: alendronate sodium (a-LEN-dro-nate)

Please read this information before you start taking FOSAMAX. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss FOSAMAX when you start taking your medication and at regular checkups.

How should I take FOSAMAX?

These are the important things you must do to help make sure you will benefit from FOSAMAX:

1. **After getting up, for the day and before taking your first food, beverage, or other medication, swallow your FOSAMAX tablet with a full glass (8-8 oz) of plain water only.**
Not mineral water
Not coffee or tea
Not juice
Do not chew or suck on a tablet of FOSAMAX.

2. **After swallowing your FOSAMAX 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.** This will help the FOSAMAX tablet reach your stomach quickly and help reduce the potential for irritation of your esophagus (the tube that connects your mouth with your stomach).
3. **After swallowing your FOSAMAX 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 is effective only if taken when your stomach is empty.
4. **Do not take FOSAMAX at bedtime or before getting up for the day.**
5. **If you have difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAMAX and call your doctor.**
6. **Take one FOSAMAX tablet once a day, every day.**

• **FDA request:** "Please revise this patient package insert using the medication guide format available in the Federal Register notice dated on December 1, 1998."
Merck agrees to revise and submit within 6 months.

• As agreed at 10/18/00 teleconference text "and...medication" retained.

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7. It is important that you continue taking FOSAMMAX for as long as your doctor prescribes it. FOSAMMAX can treat your osteoporosis or help you from getting osteoporosis only if you continue to take it.
8. 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.

What is FOSAMMAX?

FOSAMMAX 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.
- Treatment to increase bone mass in men with osteoporosis.
- The treatment of osteoporosis in both men and women receiving corticosteroid medications (for example, prednisone).
You will find more information about osteoporosis at the end of this leaflet.

How does FOSAMMAX work?

FOSAMMAX works by:

- Reducing the activity of the cells that cause bone loss
- Decreasing the faster rate of bone loss that occurs after menopause or with use of corticosteroid medications
- Increasing the amount of bone in most patients

These effects are seen as soon as three months after therapy with FOSAMMAX has begun. These effects continue as long as you keep taking FOSAMMAX. The density of bone is maintained or increased and the bone is less likely to fracture.

Who should not take FOSAMMAX?

Patients with:

- Certain disorders of the esophagus (the tube that connects your mouth with your stomach)
- Inability to stand or sit upright for at least 30 minutes
- Low levels of calcium in their blood
- Severe kidney disease
- Allergy to FOSAMMAX

Patients who are:

- Pregnant or Nursing
If you are pregnant or nursing, you should not be taking FOSAMMAX. Talk to your doctor.

What other medical problems should I discuss with my doctor?

• As agreed at 10/16/00 teleconference, second bullet retained.

Talk to your doctor about any:

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

What are the possible side effects of FOSAMAX?

Some patients may develop severe digestive reactions including irritation, inflammation or ulceration (occasionally with bleeding) of the esophagus (the tube that connects your mouth with your stomach). These reactions can cause chest pain, heartburn or difficulty or pain upon swallowing. This may occur especially if patients do not drink a full glass of water with FOSAMAX 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 after developing symptoms suggesting irritation of the esophagus.

Like all prescription drugs, FOSAMAX may cause side effects. Side effects usually have been mild. They generally have not caused patients to stop taking FOSAMAX. Some patients treated with FOSAMAX experienced abdominal (stomach) pain. This is the most commonly reported side effect. Less frequently reported side effects are:

Nausea, heartburn, irritation or pain of the esophagus (the tube that connects your mouth with your stomach), vomiting, difficulty swallowing, a full or bloated feeling in the stomach, constipation, diarrhea, black and/or bloody stools, stomach or other peptic ulcers (some severe), and gas.

Bone, muscle or joint pain, headache, or an altered sense of taste were also experienced by some patients. Rarely, a rash (occasionally made worse by sunlight) or eye pain have occurred. Allergic reactions such as hives or, rarely, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing have also been reported. Mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.

Anytime you have a medical problem you think may be related to 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. It may also be caused by certain medications called corticosteroids in both men and women. At the start osteoporosis usually has no symptoms, but it can result in fractures (broken bones). Fractures usually cause pain. Fractures of the bones of the spine may not be painful, but over time they cause height loss. Eventually the spine becomes curved and the body becomes bent over. Fractures may happen during normal, everyday activity, such as lifting, or from minor injury that would normally not cause bone to break. Fractures most often occur at the hip, spine, or wrist. This can lead to pain, severe disability, or loss of mobility.

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Osteoporosis in men and in postmenopausal women

Osteoporosis often occurs in women several years after the menopause, which happens when the ovaries stop producing the female hormone, estrogen, or are removed (which may occur, for example, at the time of a hysterectomy). 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 is important to keep your bones healthy.

Osteoporosis in men and women caused by corticosteroids

Corticosteroids can cause bone to be removed faster than it is formed, so bone loss occurs and bones become weaker. Therefore, maintaining bone mass is important to keep your bones healthy. It is important to take your corticosteroid medication as recommended by your doctor.

How can osteoporosis be treated or prevented?

- **Medication.**
Your doctor has prescribed FOSAMAX. FOSAMAX acts specifically on your bones. FOSAMAX is not a hormone and does not have the benefits and risks of estrogen (hormone replacement therapy used in postmenopausal women) elsewhere in your body.
- **Lifestyle changes.**
In addition to FOSAMAX, your doctor may recommend one or more of the following lifestyle changes:
 - **Stop smoking.** Smoking appears to increase the risk of osteoporosis.
 - **Reduce the use of alcohol.** Too much alcohol appears to increase the risk of osteoporosis and injuries that may cause fractures.
 - **Exercise regularly.** Like muscles, bones need exercise to stay strong and healthy. Exercise must be safe to prevent injuries including fractures. You should consult your doctor before you begin any exercise program.
 - **Eat a balanced diet.** Adequate dietary calcium 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.

This medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others. Keep FOSAMAX and all medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, drink a full glass of milk and contact your local poison control center or emergency room immediately. Do not induce vomiting. Do not lie down.

This leaflet provides a summary of information about FOSAMAX. If you have any questions or concerns about either FOSAMAX or osteoporosis, talk to your doctor. In addition, talk to your pharmacist or other health care provider.

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FDA 10/16/00 Facsimile with Changes from the FDA 10/18/00 Teleconference (w/2
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Whitehouse Station, NJ 08889, USA