

FOSAMAX(R)

Alendronate sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FOSAMAX. 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 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 is used for

FOSAMAX is used to treat osteoporosis and Paget's disease of the bone.

It is also used to treat or prevent osteoporosis in people who are receiving corticosteroid medicines, such as prednisone and dexamethasone.

In addition, FOSAMAX is used to prevent osteoporosis in postmenopausal women who have low bone mass.

These conditions are caused by changes in the way bone is normally maintained.

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. The menopause 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). At this time, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Osteoporosis also occurs in men but

is less common than in women.

Osteoporosis can also occur in people receiving corticosteroid medicines. If taken in high doses or for a long period of time, corticosteroid medicines can cause bone to be removed faster than it is formed. This causes loss of bone and therefore, bones become weaker and are more likely to break.

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.

Paget's disease of the bone

In Paget's disease of the bone, the process in which old bone is removed and replaced with new bone is abnormally increased. This results in new bone which is weakened and fragile. The bones most commonly affected include the skull, spine, legs, collar bone and pelvis. The weakened bones may lead to pain,

difficulty in moving, deformity and fractures.

How does FOSAMAX work?

In osteoporosis, it works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. FOSAMAX not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, FOSAMAX prevents or reverses the progression of osteoporosis. FOSAMAX starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

In Paget's disease, FOSAMAX slows down bone resorption, which allows the bone-forming cells time to rebuild normal bone.

FOSAMAX belongs to a group of non-hormonal medicines called bisphosphonates.

Before you take FOSAMAX

You should know that FOSAMAX 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.

When you must not take it

Do not take FOSAMAX if:

- * **you have an allergy to FOSAMAX 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

- * **your dentist advises you to consult your doctor first**

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

FOSAMAX has not been studied in pregnant or breast-feeding women.

Do not take FOSAMAX 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, talk to your doctor.

Do not give FOSAMAX to a child.

FOSAMAX has not been studied in children.

Before you start to take it

Tell your doctor if:

1. **you plan to become pregnant or breast-feed**
2. **you have any medical conditions, especially the following:**
 - kidney disease
 - swallowing or digestive problems, such as ulcers
3. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
4. **you have dental or jaw-bone problems or are planning to have a course of dental surgery**

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

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 if taken at the same time. These include:

- * antacids, such as Algicon*, Almacarb*, Alu-tab*, Amphojel*, De witt's* antacid, Eno* powder, Gastrobom*, Gastrogel*, Gelusil*, Meracote*, Mucaine*, Mylanta*, Rennie*, Salvital*, Simeco*, Titalac*
- * calcium supplements
- * vitamins

Therefore, take FOSAMAX 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.

However, both aspirin and FOSAMAX 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.

How to take FOSAMAX

How much to take

Take FOSAMAX only when prescribed by your doctor.

For osteoporosis in postmenopausal women and in men, the usual dose is one 10 mg tablet each day.

For osteoporosis due to corticosteroid medicines in postmenopausal women not using oestrogen, the usual dose is one 10 mg tablet each day.

For osteoporosis due to corticosteroid medicines in men and other women, the usual dose is one 5 mg tablet each day.

For the prevention of osteoporosis, the usual dose is one 5 mg tablet each day.

For Paget's disease of the bone, the usual dose is one 40 mg tablet each day.

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

Take FOSAMAX after getting up for the day. Do not take it at bedtime.

Swallow FOSAMAX whole with a full glass of plain water only.

It is important to take FOSAMAX with plain water only, not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of FOSAMAX by interfering with the absorption into the body.

Stay upright for at least 30 minutes after swallowing FOSAMAX and do not take any food, medicines or drinks other than plain tap water during this time.

Do not lie down immediately after swallowing it.

It is important to stay upright (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).

FOSAMAX 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 by interfering with its absorption into the body.

Do not chew or suck on a tablet of FOSAMAX.

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 for as long as your doctor prescribes. FOSAMAX can only prevent or treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it every day.

In Paget's disease your doctor will tell you how long to take FOSAMAX. The usual length of treatment is up to 6 months.

If you forget to take it

Skip the dose you missed and take your next dose the following morning.

If you take the forgotten tablet after you have eaten or had a drink, FOSAMAX 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.

Do not take a double dose to make up for the dose that you missed.

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 Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FOSAMAX. 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

Things you must do

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

If you become pregnant while taking FOSAMAX, 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.

If you develop a toothache or require a dental procedure, tell your dentist that you are taking FOSAMAX.

If you develop persistent pain in your leg, tell your doctor.

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.

Things you must not do

Do not give FOSAMAX 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.

Side Effects

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

FOSAMAX helps most people with osteoporosis and Paget's disease of the bone, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side 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
- * aching muscles, joints and/or bones, which rarely can be severe

* flu-like symptoms, typically at the start of treatment, such as aching muscles, generally feeling unwell, and rarely, fever.

- * swelling of joints
- * dizziness or spinning sensation
- * unusual tiredness or weakness
- * swelling of hands, ankles or feet
- * hair loss

Most of these are the more common side effects of FOSAMAX. 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, itchiness
- * mouth ulcers
- * blurred vision, pain or redness in the eye
- * symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth.

These side effects are rare, and very rarely, may be serious.

Tell your dentist and doctor immediately if you notice any of the following:

- * Jaw-bone or dental problems (including toothache). Jaw-bone problems may include infection, and delayed healing after a tooth extraction or other work that involves drilling into the jaw-bone.

These side effects are rare and may be serious.

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

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

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

If any of the following happen, stop taking FOSAMAX 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 nettle rash
- * severe skin reactions
- * black tar-like and/or bloody stools

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

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

Rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by FOSAMAX.

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

FOSAMAX is not addictive.

After using FOSAMAX

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.

Keep FOSAMAX in a cool dry place where the temperature stays below 30 degrees C. 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

What FOSAMAX looks like

FOSAMAX comes in three types of tablets:

- * *FOSAMAX 5 mg - white round tablet, with MSD 925 marked on one side and an outline of a bone image on the other.
- * FOSAMAX 10 mg - white to off-white, polished oval tablet, with 936 marked on one side.
- * FOSAMAX 40 mg - white triangular shaped tablet, with MSD 212 marked on one side and FOSAMAX marked on the other.

A box contains two blister packs with a total of 30 tablets.

* not currently available in Australia

Ingredients

Active ingredient:

- FOSAMAX 5 mg - 5 mg alendronate sodium per tablet
- * FOSAMAX 10 mg - 10 mg alendronate sodium per tablet
- * FOSAMAX 40 mg - 40 mg alendronate sodium per tablet

Inactive ingredients:

- * microcrystalline cellulose
- * anhydrous lactose
- * croscarmellose sodium
- * magnesium stearate
- * carnauba wax (10 mg tablets)

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

Supplier

FOSAMAX is supplied in Australia by:-

Merck Sharp & Dohme (Australia) Pty Limited
A.B.N. 14 000 173 508
54-68 Ferndell Street
SOUTH GRANVILLE NSW 2142

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This CMI leaflet was current at the time of printing. To check if it has been updated, please view our website, www.fosamax.com.au or ask your pharmacist.

Australian Register Numbers:

- 5 mg - AUST R 68428
- 10 mg - AUST R 73520
- 40 mg - AUST R 54380

WPC-FSM-022008

* Trademarks