

# FOSAMAX<sup>®</sup> TABLET 70MG

Alendronate Sodium (70mg)

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This leaflet answers some common questions about FOSAMAX TABLET 70MG. It is particularly important that you read the section "How to take FOSAMAX TABLET 70MG" 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 TABLET 70MG 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 TABLET 70MG is used for**

FOSAMAX TABLET 70MG (alendronate sodium) is a tablet that contains alendronate as the active ingredient.

FOSAMAX TABLET 70MG is available as a 70mg tablet for the treatment of osteoporosis.

FOSAMAX TABLET 70MG is a member of a class of non-hormonal drugs called aminobisphosphonates.

FOSAMAX TABLET 70MG helps to rebuild bone and makes bone less likely to fracture.

## **Why has my doctor prescribed FOSAMAX TABLET 70MG?**

Your doctor has prescribed FOSAMAX TABLET 70MG to treat a disease you have, known as osteoporosis. 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 a 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).

## **How can osteoporosis be treated?**

Your doctor has prescribed FOSAMAX TABLET 70MG to treat your osteoporosis. FOSAMAX TABLET 70MG not only prevents the loss of bone but actually helps to rebuilds bone you may have lost and makes bone less likely to fracture. Thus, FOSAMAX TABLET 70MG 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.



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**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 TABLET 70MG?

It is important to take FOSAMAX TABLET 70MG over the long term to continue to prevent loss of bone and to help rebuild bone you may have lost. It is, therefore, important to follow your doctor's instructions when taking FOSAMAX TABLET 70MG without skipping doses or varying from your prescribed treatment schedule.

## How FOSAMAX TABLET 70MG works

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 TABLET 70MG not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, FOSAMAX TABLET 70MG reverses the progression of osteoporosis. FOSAMAX TABLET 70MG starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

## Before you take FOSAMAX TABLET 70MG

### When you must not take it

Do not take FOSAMAX TABLET 70MG 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
- your doctor has told you that you currently have low blood calcium

### Before you start to take 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 TABLET 70MG.

### Use in pregnancy and breast feeding

Do not take FOSAMAX TABLET 70MG if you are pregnant or breast feeding.

### Use in children

FOSAMAX TABLET 70MG is not indicated for use in children.

### Use in elderly

FOSAMAX TABLET 70MG 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.

## How to take FOSAMAX TABLET 70MG

These are the important things you must do to help make sure you will benefit from FOSAMAX TABLET 70MG:

### How much to take

One 70mg tablet once weekly

### When to take it

Choose the day of the week that best fits your schedule. Every week, take one dose of FOSAMAX TABLET 70MG on your chosen day.

After getting up for the day and before taking your first food, beverage, or other medication, take your FOSAMAX TABLET 70MG with plain water only as follows: Swallow one tablet with a full glass (6-8 ounces or 180-240 mL) of plain water.



Not mineral water  
Not coffee or tea  
Not juice.

**Do not chew or suck on a tablet of FOSAMAX TABLET 70MG.**

### How long to take it

It is important that you continue taking FOSAMAX TABLET 70MG for as long as your doctor prescribes it. FOSAMAX TABLET 70MG can treat your osteoporosis only if you continue to take it.

### If you forget to use

If you miss a dose, just take one dose of FOSAMAX TABLET 70MG on the morning after you remember. Do not take two doses on the same day. Return to taking one dose once a week, as originally scheduled on your chosen day.

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### ***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.

### **While you are taking FOSAMAX TABLET 70MG**

#### ***Things you must do***

**After taking your FOSAMAX TABLET 70MG 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 TABLET 70MG and call your doctor.**

#### ***Things you must not do***

**Do not take FOSAMAX TABLET 70MG at bedtime or before getting up for the day.**

The above actions will help the FOSAMAX TABLET 70MG 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***

**After taking your FOSAMAX TABLET 70MG, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. FOSAMAX TABLET 70MG is effective only if taken when your stomach is empty.**

### **Can I drive or operate machinery while using FOSAMAX TABLET 70MG?**

There have been side effects reported with FOSAMAX TABLET 70MG that may affect

your ability to drive or operate machinery. Individual responses to FOSAMAX TABLET 70MG may vary. (See "Side effects")

### **Side effects**

Most patients do not have side effects from FOSAMAX TABLET 70MG; however, as with any medicine, FOSAMAX TABLET 70MG 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 TABLET 70MG 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 TABLET 70MG 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 TABLET 70MG may get itching or eye pain, or a rash that may be made worse by sunlight.
- 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. If you develop new or unusual pain in the hip or thigh, contact your doctor.

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

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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 calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## **How can I learn more about FOSAMAX TABLET 70MG and osteoporosis?**

You may obtain further information from your doctor and/or pharmacist, who have more detailed information about FOSAMAX TABLET 70MG and osteoporosis.

## **Storage and Disposal of FOSAMAX TABLET 70MG**

### ***Storage***

Store FOSAMAX TABLET 70MG below 30°C.

Keep FOSAMAX TABLET 70MG 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 TABLET 70MG is an oval, white tablet with the outline of a bone image on one side and the code number 31 on the other side.

### ***Ingredients***

Active ingredient: Alendronate Sodium 70mg.

Inactive ingredients: Cellulose Microcrystalline, Lactose Anhydrous, Croscarmellose Sodium, and Magnesium Stearate.

### ***MAL number***

FOSAMAX TABLET 70MG:  
MAL20013990AR

## **Product Manufacturer**

MERCK SHARP & DOHME  
(ITALIA) S.p.A.  
Via Emilia 21,  
27100 Pavia, Italy.

## **Product Registration Holder**

Merck Sharp & Dohme (Malaysia)  
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T2-9, Jaya33, No. 3 (Lot 33),  
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46100 Petaling Jaya,  
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## **Date of revision**

27/08/2013 (version 032010)