**PATIENT INFORMATION LEAFLET**

**INFORMATION FOR THE PATIENT**

**ABOUT FOSAMAX® Once Weekly 70 mg**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## SCHEDULING STATUS

S3

## PROPRIETARY NAME AND DOSAGE FORM

FOSAMAX® Once Weekly 70 mg Tablets

## 1. WHAT FOSAMAX Once Weekly 70 mg CONTAINS

FOSAMAX (alendronate sodium) Once Weekly 70 mg is a white, oval tablet that contains 70 mg alendronate as the active ingredient.

In addition, FOSAMAX Once Weekly 70 mg contains the following inactive ingredients: Microcrystalline cellulose, anhydrous lactose, croscarmellose sodium and magnesium stearate.

Contains lactose.

## 2. WHAT FOSAMAX Once Weekly 70 mg IS USED FOR

FOSAMAX Once Weekly 70 mg is a member of a class of non-hormonal drugs called bisphosphonates. FOSAMAX Once Weekly 70 mg helps to rebuild bone and makes bone less likely to fracture.

Your doctor has prescribed FOSAMAX Once Weekly 70 mg to treat a disease you have, known as osteoporosis. This will reduce the risk of developing fractures.

**How is normal bone maintained?**

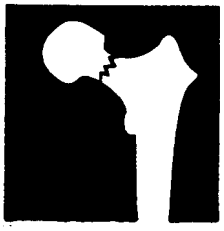
Bone undergoes a normal process of rebuilding that occurs continuously throughout your skeleton. First, old bone is removed (resorbed), then new bone is laid down (formed). This balanced process of resorbing and forming bone keeps your skeleton healthy and strong.

**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 also may occur in men. Osteoporosis often occurs in women several years after the menopause, which occurs when the ovaries stop producing the female hormone, oestrogen or are removed (which may occur e.g. at the time of a hysterectomy). The earlier a woman reaches menopause, the greater the risk of osteoporosis. Osteoporosis can also occur in men due to several causes, including aging and/or low level of the male hormone, testosterone. In all instances bone is removed faster than it is formed, so bone loss occurs and bones became 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 or spine 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 Once Weekly 70 mg to treat your osteoporosis. FOSAMAX Once Weekly 70 mg not only prevents the loss of bone, but actually helps to rebuild bone you may have lost and makes bone less likely to fracture. Thus, FOSAMAX Once Weekly 70 mg 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.



Exercise: Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.



Eat a balanced diet: Your doctor can advise you whether to modify your diet or to take any dietary supplements.



**Why is continued treatment important?**

It is important to take FOSAMAX Once Weekly 70 mg over the long term to continue to help rebuild bone you may have lost. It is therefore, important to follow your doctor's instructions for taking FOSAMAX Once Weekly 70 mg without skipping doses or varying from your prescribed treatment schedule.

## 3. BEFORE YOU TAKE FOSAMAX Once Weekly 70 mg

**Do not take FOSAMAX Once Weekly 70 mg**

- If you have certain disorders of the oesophagus (the tube that connects your mouth with your stomach).
- If you are unable to stand or sit upright for at least 30 minutes.
- If you are allergic to any of its ingredients.
- If your doctor has told you that you currently have low blood calcium.

**Take special care with FOSAMAX Once Weekly 70 mg**

- If you have or have had any medical problems or dental, including known kidney disease, any allergies and if you are or have been a smoker, tell your doctor or pharmacist.
- If you have any swallowing or digestive problems, discuss them with your doctor before taking FOSAMAX Once Weekly 70 mg.

**Pregnancy and Breastfeeding**

**Do not take FOSAMAX Once Weekly 70 mg if you are pregnant or breastfeeding. If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

**Use in children**

FOSAMAX Once Weekly 70 mg is not indicated for use in children.

**Use in elderly**

FOSAMAX Once Weekly 70 mg works equally well in and is equally well tolerated by patients older and younger than 65 years of age.

**Taking other medicines with FOSAMAX Once Weekly 70 mg**

See **"HOW TO TAKE FOSAMAX Once Weekly 70 mg"**.

**If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of FOSAMAX Once Weekly 70 mg with other medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.**

**Driving and using machinery**

There have been side effects reported with FOSAMAX Once Weekly 70 mg that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX Once Weekly 70 mg may vary (see **"What undesirable effects may FOSAMAX Once Weekly 70 mg have?"**).

## 4. HOW TO TAKE FOSAMAX Once Weekly 70 mg

These are the important things you must do to help make sure you will benefit from FOSAMAX Once Weekly 70 mg.

1. Choose the day of the week that best fits your schedule. Every week, take one FOSAMAX Once Weekly 70 mg tablet on your chosen day.
2. After getting up for the day and before taking your first food, beverage or other medication, swallow your FOSAMAX Once Weekly 70 mg tablet with a full glass of **plain water** only.
   - Not mineral water
   - Not coffee or tea
   - Not juice
   - Do not chew or suck on a tablet of FOSAMAX.



3. After swallowing your FOSAMAX Once Weekly 70 mg 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.
4. Do not take FOSAMAX Once Weekly 70 mg at bedtime or before getting up for the day.

The above actions will help the FOSAMAX Once Weekly 70 mg tablet reach your stomach quickly and help reduce the potential for irritation of your oesophagus (the tube that connects your mouth with your stomach).

5. After swallowing your FOSAMAX Once Weekly 70 mg 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 Once Weekly 70 mg is effective only if taken when your stomach is empty.
6. If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking FOSAMAX Once Weekly 70 mg and call your doctor.
7. If you miss a dose, just take one FOSAMAX Once Weekly 70 mg tablet on the morning after you remember. **Do not take two tablets on the same day.** Return to taking one tablet once a week, as originally scheduled on your chosen day.
8. It is important that you continue taking FOSAMAX Once Weekly 70 mg for as long as your doctor prescribes it. FOSAMAX Once Weekly 70 mg can treat your osteoporosis only if you continue to take it.

You should always tell your doctor about all drugs you are taking or plan to take, including those obtained without a prescription.

**If you take more FOSAMAX Once Weekly 70 mg than you should:**

**If you take too many tablets, drink a full glass of milk and contact your doctor or pharmacist immediately. If neither is available rush the patient to the nearest hospital or poison control centre. Do not induce vomiting. Do not lie down.**

## 5. SIDE EFFECTS

**What undesirable effects may FOSAMAX Once Weekly 70 mg have?**

FOSAMAX Once Weekly 70 mg 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 oesophagus (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 a **full** glass of water with FOSAMAX Once Weekly 70 mg and/or if they lie down in less than 30 minutes **or** before their first food of the day. Oesophageal reactions may worsen if patients continue to take FOSAMAX Once Weekly 70 mg after developing symptoms suggesting irritation of the oesophagus.

Some patients may experience bone, muscle and/or joint pain which is rarely severe. Patients who develop severe bone, joint and/or muscle pain should contact their physician. Most patients experienced relief after stopping FOSAMAX Once Weekly 70 mg. Patients may also experience joint swelling or swelling in their hands or legs. Transient flu-like symptoms (sometimes with fever), typically at the start of treatment, have occurred. In some cases, patients taking FOSAMAX Once Weekly 70 mg may get itching or eye pain, or a rash that may be made worse by sunlight. Hair loss has been reported. Severe skin reactions may occur. Allergic reactions such as hives, or less frequently, 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. Less frequently stomach or other peptic ulcers (some severe) have occurred. Mouth ulcers have occurred when the tablet was chewed or dissolved in the mouth.

Patients may have jaw problems associated with delayed healing and infection, sometimes 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 about these or any other unusual symptoms.

**Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

## 6. STORAGE AND DISPOSING OF FOSAMAX Once Weekly 70 mg

Do not use this medicine after the month and year following Exp./Verv.: on the carton.

Store FOSAMAX Once Weekly 70 mg in a dry place at or below 25 °C.
Keep out of reach of children.

## 7. PRESENTATION OF FOSAMAX Once Weekly 70 mg

FOSAMAX Once Weekly 70 mg Tablets are supplied in aluminium/aluminium blisters strips in packs containing 4 tablets.

## 8. IDENTIFICATION OF FOSAMAX Once Weekly 70 mg

A white, oval tablet with the outline of a bone image on one side and the code number 31 on the other side.

## 9. REGISTRATION NUMBER

35/3.2/0371

## 10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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## 11. DATE OF PUBLICATION

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