Package leaflet: Information for the patient

FOSAMAX® Once Weekly 70 mg Tablets
alendronic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- It is particularly important to understand the information in section 3 before taking this medicine.

What is in this leaflet:

1. What FOSAMAX is and what it is used for

What is FOSAMAX?
FOSAMAX is a tablet containing the active substance alendronic acid (commonly called alendronate) and belongs to a group of non-hormonal medicines called bisphosphonates. FOSAMAX prevents the loss of bone that occurs in women after they have been through the menopause and helps to rebuild bone. It reduces the risk of spine and hip fractures.

What is FOSAMAX used for?
Your doctor has prescribed FOSAMAX to treat your osteoporosis. It reduces the risk of spine and hip fractures.

FOSAMAX is a once weekly treatment.

What is osteoporosis?
Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female hormone, oestrogen, which helps to keep a woman's skeleton healthy. As a result, bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in broken bones. Although these usually hurt, breaks in the bones of the spine may go unnoticed until they cause height loss. Broken bones can happen during normal, everyday activity, such as lifting, or from minor injury that would not generally break normal bone. Broken bones usually occur at the hip, spine, or wrist and can lead not only to pain but also to considerable problems like stooped posture ('dowager's hump') and loss of mobility.

How can osteoporosis be treated?
As well as your treatment with FOSAMAX, your doctor may suggest you make changes to your lifestyle to help your condition, such as:

Stopping smoking	Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of broken bones.
Exercise	Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.
Eating a balanced diet	Your doctor can advise you about your diet or whether you should take any dietary supplements (especially calcium and Vitamin D).

2. What you need to know before you take FOSAMAX

Do not take FOSAMAX
- if you are allergic to alendronic acid or any of the other ingredients of this medicine (listed in section 6)
- if you have certain problems with your gullet (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing
- if you cannot stand or sit upright for at least 30 minutes
- if your doctor has told you that you have low blood calcium

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions
Talk to your doctor or pharmacist before taking FOSAMAX if:
- you suffer from kidney problems,
- you have, or have recently had, any swallowing or digestive problems,
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus),
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- you have been told you have low blood calcium,
- you have poor dental health, gum disease, a planned dental extraction or you don’t receive routine dental care,
- you have cancer,
- you are undergoing chemotherapy or radiotherapy,
- you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide) which are used in the treatment of cancer,
- you are taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,
- you are or have been a smoker (as this may increase the risk of dental problems).

You may be advised to have a dental check-up before starting treatment with FOSAMAX.

It is important to maintain good oral hygiene when being treated with FOSAMAX. You should have routine dental check-ups throughout your treatment and you should contact your doctor or dentist if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling.

Irritation, inflammation or ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) often with symptoms of chest pain, heartburn, or difficulty or pain upon

swallowing may occur, especially if patients do not drink a full glass of water and/or if they lie down less than 30 minutes after taking FOSAMAX. These side effects may worsen if patients continue to take FOSAMAX after developing these symptoms.

Children and adolescents
FOSAMAX should not be given to children and adolescents less than 18 years of age.

Other medicines and FOSAMAX
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of FOSAMAX if taken at the same time. Therefore, it is important that you follow the advice given in section 3.

Certain medicines for rheumatism or long-term pain called NSAIDs (e.g. acetylsalicylic acid or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as FOSAMAX.

FOSAMAX with food and drink
It is likely that food and beverages (including mineral water) will make FOSAMAX less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3.

Pregnancy and breast-feeding
FOSAMAX is only intended for use in postmenopausal women. You should not take FOSAMAX if you are or think you may be pregnant, or if you are breast-feeding.

Driving and using machines
There have been side effects (for example blurred vision, dizziness and severe bone, muscle or joint pain) reported with FOSAMAX that may affect your ability to drive or operate machinery (see section 4).

FOSAMAX contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

FOSAMAX contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take FOSAMAX

Always take FOSAMAX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take one FOSAMAX tablet <u>once a week</u>.

Follow these instructions carefully.

1) Choose the day of the week that best fits your schedule. Every week, take one FOSAMAX tablet on your chosen day.

It is very important to follow instructions 2), 3), 4) and 5) to help the FOSAMAX tablet reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube that connects your mouth with your stomach).

2) After getting up for the day and before taking any food, drink, or other medicine, swallow your FOSAMAX tablet whole with a full glass of water only (not mineral water) (not less than 200 ml), so that FOSAMAX is adequately absorbed.
   - Do not take with mineral water (still or sparkling).
   - Do not take with coffee or tea.
   - Do not take with juice or milk.

Do not crush or chew the tablet or allow it to dissolve in your mouth because of the possibility of mouth ulceration.

3) Do not lie down — stay fully upright (sitting, standing or walking) — for at least 30 minutes after swallowing the tablet. Do not lie down until after your first food of the day.

4) Do not take FOSAMAX at bedtime or before getting up for the day.

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

6) 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 supplements and vitamins. FOSAMAX is effective only if taken when your stomach is empty.

If you take more FOSAMAX than you should
If you take too many tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit, and do not lie down.

If you forget to take FOSAMAX
If you miss a dose, just take one 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.

If you stop taking FOSAMAX
It is important that you take FOSAMAX for as long as your doctor prescribes the medicine. Since it is not known how long you should take FOSAMAX, you should discuss the need to stay on this medicine with your doctor periodically to determine if FOSAMAX is still right for you.

An Instruction Card is included in the carton for FOSAMAX. It contains important information reminding you how to take FOSAMAX properly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

See your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment：
Common (may affect up to 1 in 10 people):
- heartburn; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing.

Rare (may affect up to 1 in 1,000 people):
- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing; severe skin reactions,
- pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms,
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.
- bone, muscle and/or joint pain which is severe.

Other side effects include
Very common (may affect more than 1 in 10 people):
- bone, muscle and/or joint pain which is sometimes severe.

Common (may affect up to 1 in 10 people):
- joint swelling,
- abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence,
- hair loss; itching,
- headache; dizziness,
- tiredness; swelling in the hands or legs.

Uncommon (may affect up to 1 in 100 people):
- nausea; vomiting,
- irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach,
- black or tar-like stools,
- blurred vision; pain or redness in the eye,
- rash; redness of the skin,
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment,
- taste disturbance.

Rare (may affect up to 1 in 1000 people):
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth,
- stomach or peptic ulcers (sometimes severe or with bleeding),
- narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach),
- rash made worse by sunlight,
- mouth ulcers.

Very rare (may affect up to 1 in 10,000 people):
- talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FOSAMAX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What FOSAMAX contains

The active substance is alendronic acid. Each tablet contains 70 mg alendronic acid (as sodium trihydrate).

The other ingredients are microcrystalline cellulose (E460), lactose anhydrous (see section 2), croscarmellose sodium and magnesium stearate (E572).

What FOSAMAX looks like and contents of the pack

FOSAMAX tablets are available as oval, white tablets marked with an outline of a bone image on one side and ‘31’ on the other.

The tablets are supplied in aluminium blisters in cartons in the following pack sizes: 2, 4, 8, 12 or 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Organon Pharma (UK) Limited, The Hewett Building, 14 Hewett Street, London EC2A 3NP, United Kingdom.

The Manufacturer is Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN, Haarlem, The Netherlands.

This medicine is authorised in the Member States of the EEA under the following names:

Austria	Fosamax einmal wöchentlich 70 mg Tabletten
Belgium	Fosamax 70 mg Hebdomadaire, comprimés
Denmark	Fosamax
France	Fosamax 70 mg, comprimé
Germany	FOSAMAX einmal wöchentlich 70 mg Tabletten
Greece	FOSAMAX 70 mg Μια φορά την εβδομάδα

Iceland	Fosamax vikutafla
Ireland	Fosamax Once Weekly 70 mg Tablets
Italy	FOSAMAX 70 mg compresse
Luxembourg	Fosamax 70 mg Hebdomadaire, comprimés
Netherlands	Fosamax 70 mg één tablet per week
Norway	Fosamax
Portugal	Fosamax 70 mg
Spain	FOSAMAX Semanal 70 mg comprimidos
UK	FOSAMAX Once Weekly 70 mg Tablets

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