

PACKAGE LEAFLET: INFORMATION FOR THE USER

FOSAMAX® ONCE WEEKLY 70mg TABLETS

Alendronic acid as alendronate sodium trihydrate

Read all of this leaflet carefully before you start taking this medicine, even if this is a repeat prescription.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- It is particularly important to understand the information in section 3. HOW TO TAKE FOSAMAX, before taking this medicine.

In this leaflet:

1. What FOSAMAX is and what it is used for
2. Before you take FOSAMAX
3. How to take FOSAMAX
4. Possible side effects
5. How to store FOSAMAX
6. Further information

1. WHAT FOSAMAX IS AND WHAT IT IS USED FOR

What is FOSAMAX?

Fosamax 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. FOSAMAX 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?

Osteoporosis can be treated and it is never too late to begin treatment. Fosamax not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with FOSAMAX, your doctor may suggest you make changes to your lifestyle to help your condition such as:

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

2. BEFORE YOU TAKE FOSAMAX

Do not take Fosamax

1. If you are allergic (hypersensitive) to alendronate sodium trihydrate or to any of the other ingredients
2. If you have certain problems with your gullet (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing
3. If you cannot stand or sit upright for at least 30 minutes
4. 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.

Take special care with FOSAMAX

It is important to tell your doctor before taking Fosamax if:

- you suffer from kidney problems
- you have 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 that you have low blood calcium levels
- 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 corticosteroids (such as prednisone or dexamethasone)
- 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.

Taking 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. HOW TO TAKE FOSAMAX.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

Taking 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. HOW TO TAKE FOSAMAX.

Children and adolescents

FOSAMAX should not be given to children and adolescents.

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 (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with FOSAMAX that may affect your ability to drive or operate machinery. Individual responses to FOSAMAX may vary (See POSSIBLE SIDE EFFECTS.)

Important information about some of the ingredients of FOSAMAX

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.

3. HOW TO TAKE FOSAMAX

Take one FOSAMAX tablet once a week.

Follow these instructions carefully to make sure you will benefit from FOSAMAX

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 that you follow actions 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 medication, swallow your FOSAMAX tablet whole with a full glass of *water* only (not mineral water) (not less than 200 ml or 7 fl. oz.)
 - 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.

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 continue taking FOSAMAX for as long as your doctor prescribes the medicine. FOSAMAX can treat your osteoporosis only if you continue to take the tablets.

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

4. POSSIBLE SIDE EFFECTS:

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

The following terms are used to describe how often side effects have been reported.

Very Common (occurring in at least 1 of 10 patients treated)

Common (occurring in at least 1 of 100 and less than 1 of 10 patients treated)

Uncommon (occurring in at least 1 of 1000 and less than 1 of 100 patients treated)

Rare (occurring in at least 1 of 10,000 and less than 1 of 1000 patients treated)

Very rare (occurring in less than 1 of 10,000 patients treated)

Very common:

- Bone, muscle and/or joint pain which is sometimes severe,

Common:

- 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
- 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:

- 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:

- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- 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; 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, mouth ulcers when the tablets have been chewed or sucked

Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

It will help if you make a note of what you experienced, when it started and how long it lasted.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FOSAMAX

- Keep your tablets out of the reach and sight of children
- Do not store above 30°C. Do not remove the tablets from the blister pack until you are ready to take the medicine.
- Do not use Fosamax after the expiry date which is stated on the carton and the blister pack after EXP. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Fosamax contains

Active substance

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

Other ingredients

Microcrystalline cellulose (E460), lactose anhydrous, croscarmellose sodium and magnesium stearate (E572).

What Fosamax looks like and contents of the pack

FOSAMAX Once Weekly 70 mg 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 blister packs of 4 tablets contained in an outer cardboard carton or an over-labelled outer cardboard carton.

Product procured within the EU & repackaged by the Parallel Product Authorisation Holder: PCO Manufacturing , Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

MANUFACTURER

Fosamax Once Weekly 70mg Tablets are manufactured by:

Merck Sharp & Dohme (Italia) SpA, Via Emilia 21, 27100 Pavia, Italy or Merck Sharp & Dohme B.V. P.B. 581, Waarderweg 39, NL-2003 PC Haarlem, the Netherlands.

PARALLEL PRODUCT AUTHORISATION NUMBER:

PPA 465/115/1

Fosamax is a registered trademark of Merck & Co., Inc., Whitehouse Station, New Jersey, USA.

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This medicinal product is authorized in the Member States of the EEA under the following names:

Austria FOSAMAX einmal wöchentlich 70mg Tabletten

Belgium FOSAMAX 70 mg Hebdomadaire, comprimés

Denmark Fosamax Ugetablet

Finland FOSAMAX 70 mg tabletit

France FOSAMAX 70 mg comprimé

Germany FOSAMAX einmal wöchentlich 70 mg Tabletten

Greece FOSAMAX 70 mg εβδομαδιαίο δισκίο

Iceland Fosamax vikutafla 70 mg

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 70 mg

Portugal FOSAMAX 70 mg

Spain FOSAMAX Semanal 70 mg comprimidos

Sweden FOSAMAX Veckotablett 70 mg

UK FOSAMAX Once Weekly 70 mg Tablets