

Read all 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 your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to the others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What FOSAMAX Once Weekly 70 mg Tablets is and what it is used for
2. Before you take FOSAMAX Once Weekly 70 mg Tablets
3. How to take FOSAMAX Once Weekly 70 mg Tablets (You should read this section carefully)
4. Possible side effects
5. Storing FOSAMAX Once Weekly 70 mg Tablets

FOSAMAX[®] Once Weekly 70 mg Tablets
(alendronic acid)

Each tablet contains as active substance the equivalent of 70 mg alendronic acid as 91.37 mg of alendronate sodium trihydrate.

The other ingredients (excipients) are microcrystalline cellulose, anhydrous lactose, croscarmellose sodium and magnesium stearate.

License holder:

MERCK SHARP & DOHME DE ESPAÑA, S.A.
Josefa Valcárcel, 38
28027 MADRID

Manufacturing responsible:

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Italy.

1. WHAT FOSAMAX ONCE WEEKLY 70 mg Tablets IS AND WHAT IT IS USED FOR

FOSAMAX Once Weekly 70 mg are available as oval, white tablets marked with an outline of a bone image on one side and '31' on the other.

FOSAMAX Once Weekly 70 mg are supplied in blister packs of 4 tablets.

FOSAMAX belongs to a group of non-hormonal medicines called bisphosphonates. FOSAMAX is indicated for the treatment of postmenopausal osteoporosis. FOSAMAX reduces the risk of spine and hip fractures.

2. BEFORE YOU TAKE FOSAMAX ONCE WEEKLY 70 mg Tablets

Do not take FOSAMAX Once Weekly 70 mg:

- If you have certain disorders of the oesophagus (sometimes called the gullet and is 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 alendronic acid or to any of the inactive ingredients
- If your doctor has told you that you have low blood calcium
- If you have severe renal insufficiency.

Take special care with FOSAMAX Once Weekly 70 mg Tablets:

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

- you suffer from kidney problems
- you have any allergies
- you have difficulty or pain upon swallowing
- you have or recently had digestive problems (such as irritation or ulcers of the stomach or intestines).

Important information about some of the ingredients of FOSAMAX Once Weekly 70 mg:

FOSAMAX Once Weekly 70 mg contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Taking FOSAMAX Once Weekly 70 mg Tablets with food and drink:

See section 3. HOW TO TAKE FOSAMAX ONCE WEEKLY 70 mg Tablets.

Pregnancy and breast feeding:

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

Consult your doctor or pharmacist before taking a medicine.

Children:

FOSAMAX should not be given to children.

Driving and using machines:

FOSAMAX does not affect your ability to drive or operate machinery.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines - even those not prescribed, homeopathic products, herbs and other products related to health, since it may be necessary to discontinue the treatment or adjust the doses of some of them. In these cases it is appropriate request the doctor the written instructions and make sure of understanding them correctly.

If taken at the same time with FOSAMAX Once Weekly 70 mg, antacids, calcium and other supplements and vitamins, and other medications are likely to reduce the effect of FOSAMAX. See section 3. HOW TO TAKE FOSAMAX ONCE WEEKLY 70 mg Tablets.

3. HOW TO TAKE FOSAMAX ONCE WEEKLY 70 mg Tablets

Follow these instructions unless your doctor has given you different advice.

Remember to take your medicine.

Take FOSAMAX once weekly as prescribed.

One FOSAMAX Once Weekly 70 mg Tablet is taken once a week.

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 potential for irritation of your oesophagus (the tube that connects your mouth with your stomach).

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 tablet with a full glass of *plain water* only (not less than 200 ml).**
 - **not mineral water**
 - **not coffee or tea**
 - **not juice.**

Do not chew or allow the tablet of FOSAMAX to dissolve in your mouth.

3. After swallowing your FOSAMAX tablet do not lie down — stay 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 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, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. FOSAMAX is effective only if taken when your stomach is empty.
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 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 the impression that the effect of FOSAMAX Once Weekly 70 mg is too strong or too weak, talk to your doctor or pharmacist.

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

The symptoms that can appear if you take more FOSAMAX Once Weekly 70 mg than you should are low blood calcium, low blood phosphate, and upper digestive side effects such as upset stomach, heartburn, irritation of your esophagus or stomach, or ulcer.

If you take too many tablets by mistake, drink a full glass of milk and contact your doctor or pharmacist immediately. Do not make yourself vomit and do not lie down. In case of overdosage or accidental ingestion, consult the Information Service of Toxicology. Telephone: (91) 562-0420.

If you forget to take FOSAMAX Once Weekly 70 mg Tablets:

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.

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FOSAMAX Once Weekly 70 mg may have side effects.

Side effects usually have been mild, but some patients may experience digestive disturbances which may be severe. These include irritation or ulceration of the oesophagus (the tube that connects your mouth with your stomach) which can cause chest pain, heartburn, difficulty or pain upon swallowing and/or scarring leading to narrowing of the oesophagus. These reactions may occur especially if patients do not drink a full glass of water with FOSAMAX and/or if they lie down less than 30 minutes after taking FOSAMAX or before their first food of the day. Oesophageal reactions may worsen if patients continue to take FOSAMAX after developing symptoms suggesting irritation of the oesophagus.

Other side-effects are:

Common >1% and <10% (less than 1 per 10 but more than 1 per 100 patients)

Gastrointestinal disorders: abdominal pain, disturbed digestion, constipation, diarrhoea, flatulence, lesion in the esophagus, difficulty in swallowing, full or bloated feeling in the stomach, acid regurgitation

Musculoskeletal and connective tissue disorders: bone, muscle or joint pain

Nervous system disorders: headache

General disorders and administration site conditions: transient flu-like symptoms such as muscle pain, feeling unwell, and rarely fever that occurs at the beginning of treatment.

Uncommon 0.1% to 1% (less than 1 per 100 but more than 1 per 1000 patients)

Gastrointestinal disorders: nausea, vomiting, inflammation of the mucosal lining of the stomach, inflammation of the oesophagus, wound in the oesophagus, black stools

Skin and subcutaneous tissue disorders: rash, itching, reddening of the skin.

Rare 0.01% to 0.1% (less than 1 per 1000 but more than 1 per 10000 patients)

Gastrointestinal disorders: narrowing of the esophagus, stomach or other peptic ulcers, some were severe and some bled, mouth ulcers (when the tablets have been chewed or sucked)

Eye disorders: eye pain, diminished or hazy vision and/or see black floating spots

Metabolism and nutrition disorders: low level of calcium in the blood

General disorders and administration site conditions: allergic reactions such as hives, swelling of the face, lips, tongue and/or throat possibly causing difficulty in breathing or swallowing; rash worsened by sunlight.

Very rare (less than 1 per 10000 patients)

Skin and subcutaneous tissue disorders: isolated cases of severe skin reactions.

If you observe these adverse effects or any other not mentioned in this leaflet, contact your doctor or pharmacist.

5. STORING FOSAMAX ONCE WEEKLY 70 mg Tablets

Keep out of the reach and sight of children.

No special storage conditions are required for this medicine.

Expiration:

Do not take FOSAMAX after the expiry date, which is clearly marked on the pack.

This leaflet was approved on June 2006.