

Drug treatments for osteoporosis: Alendronate (alendronic acid or Fosamax)

What is osteoporosis?

Osteoporosis occurs when the struts which make up the mesh-like structure within bones become thin causing them to become fragile and break easily, often following a minor bump or fall. These broken bones are often referred to as 'fragility fractures'. The terms 'fracture' and 'broken bone' mean the same thing. Although fractures can occur in different parts of the body, the wrists, hips and spine are most commonly affected. It is these broken bones or fractures which can lead to the pain associated with osteoporosis. Spinal fractures can also cause loss of height and curvature of the spine.

What is alendronate?

Alendronate is one of the bisphosphonate drug treatments which are widely used to reduce the risk of broken bones in people with osteoporosis. Most people take it as a weekly tablet but it is also available as a weekly oral solution, effervescent tablet, or as a daily tablet.

Why do I need a drug treatment for osteoporosis and how do the bisphosphonates work?

Drug treatments are prescribed if you have osteoporosis and are at a high risk of broken bones. These treatments help strengthen your bones and reduce your risk of having fractures. They do not help the pain that occurs when bones break. Bone is constantly being broken down (resorption) and rebuilt (formation) by specialist bone cells. This is called bone remodelling. When this becomes out of balance and more bone is broken down than is rebuilt, osteoporosis occurs. Bisphosphonates such as alendronate, known as antiresorptive drugs, inhibit the cells that wear down bone (osteoclasts) and as a consequence improve bone strength.

Which products contain alendronate?

Alendronic acid*

Dose	70mg weekly tablet
Licensing details	F M S H GIOP

Fosamax once weekly

Dose	70mg weekly tablet
Licensing details	F S H

Alendronic Acid Oral Solution

Dose	Oral solution (drink) containing 70mg alendronate taken weekly
Licensing details	FSH

Binosto

Dose	Effervescent tablet for oral solution (drink) containing 70mg alendronate taken weekly
Licensing details	FSH

Fosamax

Dose	10mg daily tablet
Licensing details	F M GIOP S H

Fosavance

Dose	Weekly tablet containing 70mg alendronate & 2800 iu vitamin D3
Licensing details	F S H (for postmenopausal women with osteoporosis at risk of vitamin D insufficiency)

Key: **F** = Post-menopausal women **M** = Men **S** = shown to reduce the risk of broken bones in the spine **H** = shown to reduce the risk of a broken hip **GIOP** = shown to reduce the risk of broken bones in people who have osteoporosis caused by glucocorticoid ("steroid") medication.

* A generic (non-branded) form of alendronate

A licensed drug has been checked for safety and effectiveness and can be prescribed by a doctor for a specific condition. Sometimes an unlicensed drug will be given at the discretion of your doctor e.g. those licensed specifically for women may be prescribed for men.

How can I get the most out of my drug treatment?

1. Be informed

Find out about your drug treatment so that you can be involved in decisions being made and you will know what to expect. Talk to your doctor and/or contact the Helpline at the Royal Osteoporosis Society if you have any questions or concerns.

2. Make sure the drug is properly absorbed

Regardless of whether you are taking the tablet or oral solution you will be instructed to take alendronate at least 30 minutes before the first food or drink (other than plain tap water) of the day. It is also important that you avoid any other medication during this time. This instruction is important because alendronate will only be absorbed if taken on an empty stomach. If you are taking a calcium supplement it is important to leave at least 3-4 hours after taking your alendronate as calcium will prevent its absorption.

3. Make sure alendronate is the treatment for you

If you have one of the following, alendronate may not be appropriate for you:

- If you cannot swallow tablets whole due to a physical problem or abnormality in your gullet. The oral solution or injectable treatment may be more appropriate for you.
- If you suffer with Barrett's oesophagus.
- If you have severe kidney problems.
- If you are pregnant or breast feeding (although only licensed for post-menopausal use, occasionally alendronate may be prescribed by specialists for younger women)

4. Continue to take your tablets regularly for the correct length of time

Alendronate is generally prescribed long term so you need to be happy with the treatment. Although it is important that you take the medication as instructed, missing the odd week will probably not have an impact on your bone health in the long run but you should avoid this if you can. If you continually forget or struggle to take your medication it would be sensible to speak to your doctor about other treatment options that you may find easier to take.

Ask your doctor about how long you need to take your osteoporosis treatment. The current advice from the UK drug regulatory organisation (MHRA) is for a formal treatment review after about five years, primarily because of the potential (but rare) risk of atypical fractures (see our factsheet on atypical (unusual) thigh bone fracture for more information

about this). At this review your doctor will make sure that the drugs are still needed, that they aren't causing side-effects and also that the benefits of continuing to take the drug continue to outweigh any potential harm. You may be advised to continue to take the drug, have a "pause" in your treatment or be advised to stop taking it altogether. Because of its structure alendronate will continue to have an effect on bone and provide some benefit even after it is stopped. Your doctor will be able to advise you on what is best for you based on your individual circumstances.

5. Lead a healthy lifestyle to keep your bones strong

Factors that can help to maintain healthy bones are a well-balanced diet with adequate calcium rich foods, safe exposure to sunlight to obtain vitamin D, regular weight bearing exercise, avoiding smoking and keeping alcohol consumption within the recommended limits.

If you have been diagnosed with osteoporosis and are taking a drug treatment, you may need to boost your calcium intake up to around 1000mg a day. Your doctor can prescribe supplements of calcium and/or vitamin D if you need them.

6. Understand the risk of side effects and what can be done to reduce them

As with any drug, there are potential side effects with alendronate. It is important to remember that:

- Most people will not experience side effects or if they do, they are short lived.
- Not all the symptoms you may read about online or see listed on your patient information leaflet are necessarily caused by the drug. Symptoms that have been reported by patients taking part in the research trials may be included as possible side effects even if they were seen in as many people who took the placebo (dummy treatment) as those taking alendronate. So common conditions such as dizziness, vertigo, joint swelling, itching and hair loss will often be reported in this way and people may think they are due to their treatment. We can only be sure that such symptoms are likely to be caused by alendronate if they were seen in more patients treated with alendronate than with placebo. The symptoms overleaf are those that can be thought of as "true side effects."

If you are taking medications for other conditions it is important to establish that it is not these that are causing your side effects. Talk to your doctor who may be able to suggest ways of investigating this further.

The full list of possible side effects can be found in the leaflet that accompanies your tablets.

If you experience these or any other symptoms which you think may be due to this medicine, speak with your doctor or pharmacist about other treatment options.

As more research findings become available more symptoms may be found to be “true side effects” so information could change in the future.

What side effects can alendronate cause?

Potential side effect	How common is it?	What can I do to reduce the risk of this occurring?
Inflamed food pipe (oesophagus), sore throat and swallowing difficulties. Heartburn	Thought to be around 1 in 10	To make sure the medication doesn't stick in your food pipe where it can cause irritation, remain standing or sitting for at least half an hour after swallowing the medication with a full glass of plain water. Try to avoid bending forward during this time. If you get heartburn that doesn't resolve, let your doctor know. There are other treatment options including those given by injection or infusion (drip) that are less likely to cause these problems.
Bone, joint or muscle pain	4 in 100 in the treatment group compared to 2.5 in 100 in placebo group	This is sometimes an initial response that often improves as your body adjusts to the new medicine and may be alleviated by taking a pain reliever such as paracetamol. Occasionally this is a long term problem in which case speak to your doctor about other treatment options
Diarrhoea	3 in 100 in the treatment group compared to 1.8 in 100 in placebo group	In the short term drink plenty of water to replace any lost fluids. If the problem persists talk to your doctor about other drug treatment options
Constipation	3 in 100 in the treatment group compared to 2 in 100 in placebo group	Try to eat a well-balanced diet containing plenty of fibre and drink plenty of water. Constipation may also be caused by calcium supplements which are often prescribed with alendronate. If you are also taking these speak to your doctor about stopping or cutting down the dose of the calcium supplement- if you do this, make sure you get enough calcium from your food and vitamin D from safe sunlight exposure.
Headache	3 in 100 in the treatment group compared to 1.5 in 100 in placebo group	Take a simple pain reliever like paracetamol although if the headache continues, speak with your doctor
Inflammation in the eye (uveitis and scleritis) causing eye pain or disturbed vision	1 in 100 to 1 in 1000	If you have an existing inflammatory eye condition or develop any symptoms such as a painful red eye you should see your doctor.

Are there any other health risks associated with alendronate?

Osteonecrosis of the jaw

This is an extremely rare jaw problem in which there is delayed healing in the mouth usually following invasive dental procedures. The general advice is to maintain good oral hygiene and receive routine dental checkups

Atypical (unusual) thigh bone fracture

This is an unusual and rare type of thigh bone fracture which can occur after long term treatment and as a result of little or no force

For more information see our factsheets on these very rare conditions

The Medicines and Healthcare products Regulatory Agency (MHRA) is the organisation in the UK that makes sure drugs and medical devices work and are acceptably safe.

This information reflects current evidence and best practice but is not intended to replace the medical advice provided by your own doctor or other healthcare professional.

This is one of many information resources available about osteoporosis and bone health. View the range at theros.org.uk and order more by calling us on **01761 471 771** or emailing info@theros.org.uk

President: HRH The Duchess of Cornwall. Formerly known as the National Osteoporosis Society.
Royal Osteoporosis Society is a registered charity no. 1102712 in England and Wales, no. SC039755 in Scotland, and no. 1284 in Isle of Man. Registered as a company limited by guarantee in England and Wales no. 4995013, and foreign company no. 006188F in Isle of Man.
Registered address: Camerton, Bath, England, BA2 0PJ

For osteoporosis information and support contact our free specialist nurse Helpline:

 nurses@theros.org.uk

 **0808 800 0035**

This information is provided free of charge. If you would like to become a member or support the charity with a donation, please go online or call us:

 theros.org.uk

 **01761 473 287**



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