

Drug treatments for osteoporosis: Zoledronic acid (Aclasta)

What is osteoporosis?

Osteoporosis occurs when the struts that form the mesh-like structure inside bones become thin. This causes the bone to become fragile and break easily, even after a minor bump or fall. You might hear these breaks described as 'fragility fractures'. The terms 'fracture' and 'broken bone' mean the same thing.

Fractures can occur in many parts of the body, but they are most common in the wrists, hips and spine. It's these broken bones that can cause pain, rather than osteoporosis itself. Spinal fractures can also cause height loss and a curved spine.

What is zoledronic acid?

Zoledronic acid is one of the bisphosphonate drug treatments that are used to reduce the risk of broken bones in people with osteoporosis.

It is given as an intravenous infusion (drip) once a year, usually in a hospital clinic, although some GP surgeries are able to give intravenous drugs. The drug is given slowly, typically over 15 minutes via a needle inserted into a vein.

Your doctor will usually only recommend this infusion if bisphosphonates in tablet form are unsuitable for you.

If zoledronic acid is prescribed and you have recently broken your hip, it is recommended that zoledronic acid is given two or more weeks after your hip repair surgery.

Why do I need an osteoporosis drug treatment and how do 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 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 zoledronic acid, known as antiresorptive drugs, inhibit the cells that wear down bone (osteoclasts) and as a consequence improve bone strength.

Which products contain zoledronic acid?

Aclasta*

Dose	5mg once yearly intravenous infusion ('drip')
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Licensing details	F M S H GIOP
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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 zoledronic acid is also available

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.

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. Ask your doctor for a copy of the Patient Information leaflet which describes how the drug is given and the possible side effects. It is important that you gather as much information as possible and discuss any worries you may have prior to having the first infusion.

2. Make sure you have enough calcium and vitamin D

It is important that you have adequate calcium and vitamin D whilst taking zoledronic acid. Many people take these in supplement form if they are not able to get sufficient calcium from their diet or, in the case of vitamin D, safe sunlight exposure. Your doctor may recommend blood tests prior to the infusion to check that your kidneys are functioning correctly and that your calcium and vitamin D levels are satisfactory. Make sure you drink enough fluids – at least one or two glasses – before and after the infusion to prevent dehydration.

3. Make sure zoledronic acid is the treatment for you

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

- If you have hypocalcaemia (this means that the levels of calcium in your blood are too low)
- If you have severe kidney problems.
- If you are pregnant or breast feeding (although only licensed for post-menopausal use, occasionally it may be prescribed by specialists for younger women).

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

Zoledronic acid is generally prescribed for three years in the first instance so you need to be happy with the treatment. The current advice from the UK drug regulatory organisation (MHRA) is for a regular formal treatment review, primarily because of the potential (but rare) risk of atypical fractures. This is likely to be after 3 years of treatment. At this review your doctor will assess whether the drug treatment is still needed and also that the benefits of continuing with treatment outweigh any potential harm.

You may be advised to continue to take a treatment for osteoporosis (either zoledronic acid or an alternative treatment), have a 'pause' in your treatment or be advised to stop taking it altogether. Because of its structure zoledronic acid 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.

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.

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 zoledronic acid. 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 zoledronic acid.

So common conditions such as dizziness and headaches 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 zoledronic acid if they were seen in more patients treated with zoledronic acid 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.

As this drug treatment is given as a yearly infusion you may worry that you will experience side effects that you can do nothing about. Although this is an understandable concern this does not appear to occur and although as explained you may experience side effects in the days following the infusion they are generally short lived.

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 zoledronic acid cause?

Potential side effects	How common is it?	What can I do to reduce the risk of this occurring and what should I do if I experience this problem?
Fever, chills, pain in the muscles or joints, and headache, often described as “flu-like” symptoms	Up to 1 in 3 with the first infusion (Subsequent infusions are usually much less severe)	These symptoms are very common, affecting up to 30% of people following the first infusion. They generally go away after the first couple of days following the zoledronic acid. Your doctor can recommend a mild pain reliever such as ibuprofen or paracetamol to reduce these side effects. Try not to plan any strenuous activities for the few days following your infusion in case you experience this reaction. The chance of experiencing these side effects decreases with subsequent doses of zoledronic acid.
Bone, joint or muscle pains	1 in 10 to 1 in 100	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 killer such as paracetamol. If symptoms persist speak to your doctor about other treatment options
A small increase in the incidence of serious cases of a fast and irregular heartbeat called atrial fibrillation (AF) have been seen in people taking zoledronic acid	This was noted in some but not all studies and was very uncommon. It is unclear whether the arrhythmia was caused by the treatment	Generally the benefits of bisphosphonates will outweigh this small risk but if you are worried talk to your doctor. If for any reason you think that you may have other risk factors for AF in your medical history or think you may already have the condition then a further discussion with the doctor would be recommended.
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 zoledronic acid?

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 check-ups.

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 fact sheets on these very rare conditions.

Getting more information and support

We hope this fact sheet will help you feel more informed and more confident when discussing your bone health with your medical team.

For more information about osteoporosis and bone health, including fact sheets on all available drug treatments, please visit our website at theros.org.uk/info, or order more of our printed publications.

If you need more information or support, talk to your healthcare professional.

You can also call our specialist Helpline nurses with any questions or concerns about bone health, for free, on **0808 800 035**, or email them at nurses@theros.org.uk



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This information is based on the latest evidence and clinical practice. It should not replace advice from your own healthcare professionals.

To give us feedback on this fact sheet, email us at health.info@theros.org.uk

We provide our information free of charge. To make a donation or become a member, visit theros.org.uk or call **01761 473 287**.

To view or order more information about osteoporosis and bone health:



theros.org.uk/info



01761 471 771



info@theros.org.uk

To contact our specialist nurses:



0808 800 0035



nurses@theros.org.uk

President: HRH The Duchess of Cornwall. Formerly known as the National Osteoporosis Society.

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