

Drug treatments for osteoporosis: Risedronate (Actonel)

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 risedronate?

Risedronate is one of the bisphosphonate drug treatments which are widely used to reduce the risk of broken bones in people with osteoporosis. It is available as a daily or weekly tablet. Most people take it as a weekly 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 risedronate, known as antiresorptive drugs, inhibit the cells that wear down bone (osteoclasts) and as a consequence improve bone strength.

Which products contain risedronate?

Risedronate sodium*

Dose	35mg weekly tablet or 5mg daily tablet
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Licensing details	F M S H GIOP
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Actonel once a week

Dose	35mg weekly tablet
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Licensing details	F M S H
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Actonel

Dose	5mg daily tablet
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Licensing details	F GIOP S H
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Actonel Combi

Dose	Weekly 35mg risedronate tablet. Sachet of calcium 1,000mg and vitamin D3 (880iu) taken daily on intervening 6 days
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Licensing details	F S
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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 corticosteroid medication

*A generic (non-branded) form of risedronate

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 eg those licenced 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 the dose and how often it is taken, you will be instructed to take risedronate 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 risedronate 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 risedronate as calcium will prevent its absorption.

3. Make sure risedronate is the treatment for you

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

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

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

Risedronate is generally prescribed long term so you need to be happy with the treatment. Although it is important that you take the tablets as instructed, missing the odd tablet 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, risedronate 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 risedronate. 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 risedronate. So common conditions such as constipation, nausea and diarrhoea 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 risedronate if they were seen in more patients treated with risedronate than with placebo. The symptoms below are those that can be thought of as “true side effects”.

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 drug treatment options.

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 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 risedronate cause?

Potential side effects	How common is it?	What can I do to reduce the risk of them occurring?
Inflamed food pipe (oesophagus), sore throat and swallowing difficulties. Heartburn	Thought to be around 1 in 10	To make sure the tablet 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 tablet with a full glass of plain water. Try to avoid bending forward during this time. If you get heart burn 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	Thought to be around 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 reliever such as paracetamol. Occasionally this is a long term problem in which case speak to your doctor about other treatment options
Headache	2 in 100 in the treatment group compared to 1 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 risedronate?

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 factsheets on these very rare conditions.

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.
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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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