

# Drug treatments for osteoporosis: Romosozumab (Evenity)

## 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 romosozumab?

Romosozumab is a new drug treatment for osteoporosis that has been shown to reduce the risk of fractures, and is prescribed by osteoporosis specialists at the hospital. It is an injection that you give to yourself once a month for 12 months. It may be suggested for you if you have a higher risk of breaking a bone. It will not be suitable for everyone.

Romosozumab is licensed\* as safe and effective but is not yet 'approved for use' in all the UK nations. Romosozumab is approved for restricted use in Scotland. It is not yet approved in England, Wales and Northern Ireland. The National Institute for Health and Care Excellence (NICE) is due to make a decision on this in 2021. It may be available on private prescription in some situations before then.

## How does romosozumab work?

People with osteoporosis break bones more easily than other people because the inner structure within bones has become thinner and may have broken down. This causes them to become weaker and break easily, sometimes following a minor bump or fall. These broken bones are often referred to as 'fragility fractures'.

Bone is constantly being broken down (known as resorption) and rebuilt 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.

Romosozumab is a monoclonal antibody which helps the cells that build bones (osteoblasts) and slows the cells that break down bone (osteoclasts). This prevents bone loss. One of the substances involved in this process is a protein called sclerostin. Romosozumab blocks the way that sclerostin works. By doing this, it makes bones stronger and reduces the risk of your bones breaking. It doesn't relieve the pain caused by fractures so you won't feel any different when you take it.

## Which products contain romosozumab?

### Evenity\*

Dose	210 mg subcutaneous injection (under the skin). This is given as two injections (one straight after the other) once a month, for 12 months
Licensing details	Romosozumab (Evenity) is licensed for the treatment of severe osteoporosis in post-menopausal women at high risk of fracture

*\*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. For example, those licensed specifically for women may be prescribed for men.*

## Who is prescribed romosozumab?

Romosozumab is licensed for women who have been through the menopause, have already had one fragility fracture and have a high risk of breaking another bone.

NICE and the Scottish Medicines Consortium (SMC) are the government organisations that make decisions about how romosozumab can be prescribed. These decisions are based on how well the drugs work and how much they cost.

In Scotland, the SMC states that this medicine is for those who have had a fracture in the last two years and are at high risk of another. In practice, this will generally mean you are someone who has had several fragility fractures, usually in the spine, and are at risk of further broken bones - and especially if you have already tried other drug treatments.

It will not be suitable for you if you have low levels of calcium in the blood (hypocalcaemia). It will also be unsuitable if you have had a heart attack or a stroke.

## Getting the most out of your treatment

### 1. Be informed

Find out about your drug treatment so that you can be involved in decisions being made and know what to expect. Talk to your doctor and/or contact our Helpline if you have any questions or concerns. If you don't already have a copy of the Patient Information Leaflet which describes how the drug is given and the possible side effects, ask for a copy. It is important that you gather as much information as possible and discuss any worries you may have before having the first injection.

### 2. Make sure romosozumab is the treatment for you

There are some conditions or situations that may mean romosozumab is not suitable for you. Have a chat with your doctor if romosozumab is being considered for you and any of the below apply. These are:

- A history of heart attack or stroke.
- A low blood calcium level (hypocalcaemia). This must be corrected by an adequate intake of calcium and vitamin D before starting on romosozumab as very rarely romosozumab treatment can cause blood calcium levels to drop significantly.
- If you are pregnant or breastfeeding (although only licensed for women after the menopause, occasionally it may be prescribed by specialists for younger women).
- If no other medicine is suitable for you - you will need a follow-on treatment after romosozumab to maintain the benefits for your bones.

### 3. Make sure you take (and store) the treatment correctly

Following the instructions for storing and giving yourself the injections will ensure that it will have the most benefit for your bones.

**How is it taken?** Romosozumab is given as two injections just under the skin, once a month for 12 months. You, a family member or a carer can give the injection. You will be provided with instructions and shown how to do this. The second injection must be given immediately after the first one but at a different injection site. Injections can be given either in the stomach area (abdomen) or thigh.

The outer area of your upper arm can also be used as an injection site, but only if someone else is giving you the injection. If you plan to use the same injection area for the second injection, a different injection spot should be used.

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

Romosozumab is prescribed for a one year period, so it is important that you are happy with the treatment. It will reduce the risk of broken bones during this time. After one year, it must be followed by an alternative treatment for osteoporosis, such as a bisphosphonate, for protection to be sustained. This is because the benefits wear off very quickly. Your doctor will be able to advise you on what is best for you, based on your individual circumstances.

### 5. Make sure you have enough calcium and vitamin D

It is important that you have adequate calcium and vitamin D while taking romosozumab.

Your doctor will want to make sure you have enough calcium, either from your diet or from supplements. They may prescribe calcium and vitamin D to help prevent low calcium levels in your blood before you start your treatment and while you take romosozumab.

### 6. Reduce the risk of side effects

You may be worried about potential side effects and long-term risks of taking a drug treatment, or struggling to balance these against the benefits for your bones.

Find out more so that you aren't put off taking a treatment. Most people don't get side effects, and the risk of long-term health problems is usually much smaller than the risk of you breaking a bone if you don't have a drug treatment.

Remember that if the drug treatment is taken correctly, most people will not experience any problems at all. Any side effects can be an initial response to the drug and will go after a short time.

Not all the symptoms you see listed on the patient information leaflet are necessarily caused by the drug. We can only be sure that such symptoms are likely to be caused by romosozumab if they were seen in more patients treated with romosozumab than with the 'dummy drug' in the trials.

The symptoms below are those that can be thought of as 'true side effects'. As more research findings become available, more symptoms may be found to be true side effects, so information could change in the future.

If you are taking medications for other conditions, it's important to make sure that it is not these that are causing your side effects. Talk to your healthcare professional who may be able to suggest ways of investigating this further.

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

Some people worry that if they experience side effects with an injection that they can do nothing about it. Although this is an understandable concern, side effects are generally short lived.

Potential side effects	How common is it?	What can I do to reduce the risk of this occurring?
Joint pain	1 in 8 (though this was only very slightly higher than the placebo group.)	Take a simple pain reliever, such as paracetamol. If the problem persists, speak to your doctor.
Headache	1 in 17 (though this was only very slightly higher than the placebo group.)	Take a simple pain reliever, such as paracetamol. If the problem persists, speak to your doctor.
Cold-like symptoms	1 in 8 (though this was only very slightly higher than the placebo group, and only seen in one study.)	To help you get better more quickly: <ul style="list-style-type: none"> <li>• rest and sleep</li> <li>• keep warm</li> <li>• drink plenty of water (fruit juice or squash mixed with water is OK) to avoid dehydration</li> <li>• gargle saltwater to soothe a sore throat</li> </ul>
Heart attack	1 in 125	You shouldn't take romosozumab if you have had a heart attack or stroke in the last year.
Stroke	1 in 166	
Major Adverse Cardiac Event (this refers to any potential heart problems)	1 in 90	The listed risks will depend on your own medical history – you will need to discuss with your doctor how they apply to you and whether this drug is suitable.

#### Other health risks associated with romosozumab

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 that can occasionally occur as a result of little or no force

**We understand that you need to make decisions that are right for you. If you are still unclear or need more information about romosozumab or other drug treatments, do contact our Helpline or discuss with your healthcare professional**

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](https://theros.org.uk) and order more by calling us on **01761 471 771** or emailing [info@theros.org.uk](mailto:info@theros.org.uk)

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

 [nurses@theros.org.uk](mailto: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](https://theros.org.uk)

 **01761 473 287**



**theros.org.uk**

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