

Drug treatments for osteoporosis: Romosozumab (Evenity®)

Romosozumab is a new injectable drug treatment for some women with osteoporosis. It works by speeding up the cells that make new bone, as well as slowing down the cells that break down bone. This can help to prevent bone loss and strengthen your bones.

It isn't suitable for everyone, but may be an option if you've already broken a bone due to osteoporosis and are at high risk of breaking another. It can be used as a first drug treatment for osteoporosis, or for women who have tried standard treatments but are still breaking bones.

Who is this fact sheet for?

This information may be helpful if you (or someone close to you):

- have been through the menopause and have broken a bone due to osteoporosis
- have been told by your healthcare professional that you have a high risk of breaking another bone
- have been advised to consider taking a drug treatment to help lower this risk.

It includes the following information:

- What is osteoporosis?
- What is romosozumab?
- How does romosozumab work?
- Who can have romosozumab?
- How do you take romosozumab?
- Getting the most out of your treatment
- Getting more information and support

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 romosozumab?

Romosozumab (brand name: Evenity®) is a new drug treatment for osteoporosis. It can help to reduce the risk of fractures in women who have already broken a bone. It's usually prescribed by specialists at a hospital (not by GPs) and is only an option for some women.

How does romosozumab work?

The inside of our bones is constantly being broken down and rebuilt by specialist bone cells. This process, known as bone remodelling, helps to keep bones healthy and strong.

Osteoporosis occurs when this process becomes out of balance and more bone is broken down than formed, leading to bone loss.

Romosozumab is a type of medication called a monoclonal antibody. It helps the cells that build bone (osteoblasts) and slows the cells that break down bone (osteoclasts).

One of the substances involved in this process is a protein called sclerostin. Romosozumab blocks the way that sclerostin works. By doing this, it can help to make bones stronger and reduce your risk of breaking bones.

Like any osteoporosis drug, romosozumab won't reduce the pain caused by broken bones. This means you won't feel any different when you take it. But there are other treatments and ways to manage pain.

Who can have romosozumab?

Romosozumab will only be an option if you:

- have been through the menopause, **and**
- have broken a bone due to osteoporosis, **and**
- have a high risk of breaking another bone.

In practice, romosozumab will usually only be offered to post-menopausal women who've had one or more spinal fractures, or whose risk of breaking another bone is likely to be high because of very low bone density or several other risk factors.

Where is romosozumab available?

Romosozumab is a new treatment, so it may not yet be available everywhere.

In **England** and **Wales**, romosozumab was approved for use on the NHS in May 2022. This means it should be available in most places, for women who have been through the menopause and have broken a bone due to osteoporosis in the last two years, meaning they are at high risk of breaking another.

In **Scotland**, it is available for women who have been through the menopause and have broken a bone due to osteoporosis in the last two years.

In **Northern Ireland**, the Department of Health has endorsed the guidance used in England and Wales. This means you should be able to get romosozumab if your doctor thinks it is suitable for you.

It's worth bearing in mind that GPs won't usually prescribe romosozumab, so you'll probably need to see a specialist at a hospital. If your referral is likely to be delayed, your GP may recommend starting you on a different drug treatment, to help protect your bones while you wait.

When is romosozumab not suitable?

You won't be able to have romosozumab if you:

- have had a heart attack or stroke (see page 4)
- have a low blood calcium level (hypocalcaemia) – you'll need to increase your intake of calcium and vitamin D before you can start romosozumab.

Pregnancy and breast-feeding

Romosozumab is only licensed for use in women who have been through the menopause. It hasn't been tested in pregnant or breast-feeding women. This means we don't yet know whether it might affect a child in the womb or while being breast-fed. If you're pregnant or breast-feeding, ask your doctor about treatments that may be suitable for you.

Men with osteoporosis

Romosozumab is only licensed for use in women, as there hasn't been enough research to show it is safe and works well in men. Occasionally, a doctor may agree to prescribe a medication outside its licence – known as 'off-label' use. But in practice, you probably won't be able to have romosozumab if you're a man.

How do you take romosozumab?

Romosozumab involves giving yourself two injections just under the skin, once a month for 12 months. You'll have a total dose of 210mg per month (105mg in each injection).

You'll be given instructions and shown how to give yourself the injections. If you can't do them yourself, a family member or carer can do them for you.

You should do your two injections together each month – one straight after the other. You can give them into your stomach area (abdomen) or your thigh. It's best to choose a different part of the body for each injection. If this isn't possible, don't give both injections in the exact same place.

You can also have the injections in the outer area of your upper arm, but only if someone else does this for you.

Getting the most out of your treatment

Be informed

Find out about your drug treatment so you can be involved in decisions and know what to expect. It's important to gather as much information as possible before making a decision that's right for you.

Make sure you read the Patient Information Leaflet that comes with your treatment. This explains how to use romosozumab and the possible side effects. If you don't have a copy, ask your doctor for one.

If you have any questions or concerns, before or during your treatment, talk to your doctor or contact our specialist Helpline nurses.

Make sure romosozumab is right for you

There are some conditions or situations where romosozumab may not be suitable for you (see page 2). Make sure your doctor knows if any of these apply.

Romosozumab may also not be suitable if you can't take other treatments for osteoporosis, such as bisphosphonates. This is because you'll need to start another treatment after your 12-month course of romosozumab, as the drug's benefits will start to wear off when you stop taking it.

It's important to discuss this with your doctor before starting treatment. They'll be able to advise you on suitable follow-on treatments to make sure your bones stay protected.

Store and take your treatment correctly

Follow the instructions for storing and giving yourself the injections – this will ensure that it has the most benefit for your bones.

You'll need to use romosozumab for a year, so it's important to be happy with your decision to start treatment. Make sure you use the treatment as prescribed – this will help to reduce your risk of broken bones during this time.

Make sure you get enough calcium and vitamin D

It's important to have enough calcium and vitamin D while you're on romosozumab. Your doctor may prescribe calcium and vitamin D supplements before and during your treatment with romosozumab, to make sure you are getting enough.

Understand the drug's benefits and the possible side effects

You may be worried about the possible side effects and long-term risks of taking a drug treatment. This can make it difficult to weigh up the pros and cons of taking a drug treatment for osteoporosis.

If you take the time to understand the benefits and possible risks of taking romosozumab, this may help to reassure you, so that you aren't put off taking it.

Most people don't get any side effects at all. And if you choose to take a drug treatment, such as romosozumab, your risk of long-term health problems will usually be much smaller than your risk of breaking a bone if you don't have treatment.

Some people worry that if they get side effects after an injection, they won't be able to do anything about it. This is an understandable concern. But remember that if you take romosozumab correctly, you're unlikely to experience any problems. And even if you do get side effects at first, these will usually improve after a short time on treatment.

Only some of the problems you see listed on the Patient Information Leaflet will actually be caused by the drug. In clinical trials, many of the listed problems were just as common in people taking a 'placebo' (dummy drug) as in people taking romosozumab.

The problems listed on page 4 are thought to be the main 'true' side effects of romosozumab. This list may change over time, as more research is carried out and we learn more about the treatment.

If you experience any problems that you think may be due to romosozumab, tell your doctor or pharmacist. If you're taking any other medications, it's possible that these other drugs may be causing side effects. Your doctor or pharmacist may suggest ways to investigate this further. They can also talk to you about other possible treatment options.

Side effect	How common is it?	What can I do about it?
Joint pain	1 in 8 (only very slightly higher than the placebo group)	Take a simple pain-relieving medication, such as paracetamol. If the pain continues, talk to your doctor.
Headache	1 in 17 (only very slightly higher than the placebo group)	Take a simple pain-relieving medication, such as paracetamol. If the pain continues, talk to your doctor.
Cold-like symptoms	1 in 8 (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"> • rest and sleep • keep warm • drink plenty of water to avoid dehydration (fruit juice or squash is also okay) • gargle saltwater to soothe a sore throat.

Other health risks associated with romosozumab

Osteonecrosis of the jaw	This is an extremely rare problem where healing is delayed inside the mouth, usually after invasive dental treatment. The general advice is to maintain good oral hygiene and go for routine dental check-ups.
Atypical (unusual) thigh bone fracture	This is an unusual and rare type of thigh bone fracture that can occasionally occur, even with little or no force.

Why isn't romosozumab used after a heart attack or stroke?

Some research shows that people taking romosozumab may be more likely to have a heart attack or stroke. The drug has been tested in two main clinical trials so far. One of these recorded an increase in heart problems and strokes, but the other didn't. This means we don't yet fully understand the risk of these problems with romosozumab.

Because of this uncertainty, romosozumab is currently only given to people with a low risk of heart problems. Your doctor should consider your heart health before recommending romosozumab.

Getting more information and support

For more information about osteoporosis and bone health, including fact sheets on all available drug treatments, 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 or living with osteoporosis, for free, on **0808 800 0035** 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**.

President: Her Majesty The Queen Consort (formerly HRH The Duchess of Cornwall).
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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