Royal Osteoporosis Society
Better bone health for everybody

Drug treatments for osteoporosis: Denosumab

Denosumab (also known as Prolia®) is a drug treatment for osteoporosis. It can help to strengthen bones, making them less likely to break. It is given as an injection every six months. Denosumab isn't usually given as a first treatment for osteoporosis. It'll probably only be an option if you've already tried one of the more common drug treatments, or if other treatments aren't suitable for you.

Who is this fact sheet for?

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

- have osteoporosis or a high risk of fractures (broken bones), and want to know how denosumab can help
- want to understand the advantages and disadvantages of denosumab, including the possible side effects.

It includes the following information:

What is osteoporosis?

Osteoporosis is a condition where the bones become weaker 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 affect almost any bone, 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 denosumab?

Denosumab (brand name: Prolia®) is a drug treatment for osteoporosis. It is a type of medication called a monoclonal antibody.

Why do I need a drug treatment?

Doctors follow guidelines when deciding whether to offer treatments. If your doctor has recommended denosumab, this means your risk of breaking a bone is high enough to need a drug treatment. Denosumab can help to strengthen and protect your bones, making you less likely to break a bone in the future.

It's your choice whether to have denosumab or not. There's information on page 5 to help you decide.

What does denosumab do and how does it work?

Denosumab can help to make your bones stronger and reduce your risk of broken bones, including hip and spinal fractures.

Bones are made up of living tissue. The inside of our bones is constantly being broken down and rebuilt by specialist bone cells. As long as this process is in balance, your bones should stay healthy and strong.

But if the process becomes out of balance, our bodies can start to break down more bone than we build. This can cause the bones to become weaker and more likely to break easily.

Denosumab works by blocking the formation and activity of cells that break down bone. This helps to restore the balance and make your bones stronger.

You may still break a bone while taking denosumab. If this happens, it doesn't necessarily mean the drug isn't working. No medication can stop all fractures, but taking denosumab will make them much less likely.

Denosumab is not a pain-relieving medicine, so it won't reduce the pain caused by broken bones. But there are other treatments and ways to manage pain. There's information about these on our website at **theros.org.uk/info**

Who can have denosumab?

Denosumab may be suitable if you have osteoporosis, or if your risk of breaking a bone is high enough to need a drug treatment. You might be offered it as a first treatment. But it will usually only be an option if you've already tried a different drug treatment for your bones, or if other drugs aren't suitable for you.

It is licensed for use in women who have been through the menopause, and for men. Doctors will occasionally offer denosumab to younger women.

When is denosumab not suitable?

Denosumab may not be suitable if you:

- have a low blood calcium level (hypocalcaemia) – you'll need to increase your intake of calcium and vitamin D before you can start denosumab
- have an intolerance to sorbitol (a type of sugar)
- are pregnant or breast-feeding.

How is denosumab given?

You'll have an injection every six months, usually at the hospital or GP surgery.

The injection will be given through a needle just under the skin in either:

- your abdomen (tummy)
- the top of your thigh
- your upper arm.

The needle is thin and people often say they feel very little pain.

It's important to have the injection every six months. This is because the effects of the drug wear off very quickly. You can have injections up to four weeks early or late, if you need to.

You should get a patient reminder card, but it's a good idea to make a note in your diary or set a reminder on your phone, to help you remember.

Before you start denosumab

Before you start having denosumab, make sure you talk to your doctor about what will happen when you stop having it. Your risk of spinal fractures can increase very quickly when you stop having denosumab, particularly if you've been on it for more than two years. This means you will need to start another drug straightaway.

It's very important to plan ahead with your doctor. If you can't – or are not willing to – take another drug after denosumab, it probably isn't the right treatment for you. Your doctor may refer you to a hospital specialist who can talk to you about your options.

How will my treatment be monitored?

You'll have an appointment every six months to receive your injection. Contact your healthcare professional if you have any problems in-between your appointments. They may be able to suggest ways to help manage any side effects (see page 3).

You should have a blood test before each injection, unless your doctor decides you don't need one. This is to check your calcium levels, how well your kidneys are working, and sometimes your vitamin D levels. Some people will also have a blood test two weeks after each injection – for example if their kidneys aren't working as well as they should.

If you break a bone while having denosumab, speak to your GP. Breaking a bone doesn't necessarily mean your treatment isn't working. But it may be a good idea to have a bone health assessment.

After about five years on denosumab you should have a formal treatment review. At this review, your doctor will check if denosumab is still the right treatment for you.

You may have a bone density scan, which will give your doctor some information about your bone strength. But they will need to consider other things as well, such as whether you've broken any bones since starting on denosumab.

While there's no clear way to prove for certain that your treatment is working, research has shown that denosumab does lower the risk of broken bones.

After your review, your doctor may advise you to:

- stay on denosumab for another five years
- change to a different drug treatment – usually a type of drug called a bisphosphonate
- see a specialist if you want to stop denosumab and need advice on what to do next.

There is no formal guidance about how long people should have denosumab for. But most people stay on it for several years before moving to a different drug treatment. Your doctor can advise you on what's best for you, based on your own situation.

Can I stop having denosumab for a while?

You may have heard the term 'treatment pause' when talking about drug treatments. This is where you stop treatment for a year or two, if this is safe for you.

It is sometimes an option for people taking a bisphosphonate, such as alendronate or zoledronate. Those drugs keep helping your bones for a while after you stop taking them.

Denosumab wears off quickly, so **a treatment pause won't be an option**.

What are the possible side effects?

As with any drug, denosumab can sometimes cause side effects. The most common side effects are listed on page 4, along with some rare problems that might very occasionally happen after several years of treatment.

It is important to remember that side effects are less common than many people think. Most people on denosumab don't have any problems. Even if you do get side effects at first, they usually improve quickly and there are ways to manage them.

For a full list of possible side effects, look at the patient information leaflet that comes with your treatment. If you don't have a copy, ask your doctor or pharmacist for one.

It's important to understand that many of these problems aren't actually caused by the drug. When a medicine is first tested, the people taking it have to report anything unusual to the researchers. The problems they report are often just as common in people who aren't taking the drug.

The problems listed on page 4 are the main side effects that were seen more often in people on denosumab, rather than a dummy drug.

If you do get any side effects that don't go away, it may help to:

- make sure the problem isn't caused by any other medication you are taking
- tell your doctor or pharmacist, who may be able to help find out what is causing the problem
- ask your doctor or pharmacist about other treatments that may suit you better.

Possible side effects of denosumab:

The following table has information on the main side effects and how common they are. For example, fewer than 1 person in every 100 people who have denosumab will get a severe skin infection. The other 99 in every 100 people who use the drug will not have this problem.

Side effect	How common is it?	What can I do about it?
Severe skin infection	Less than 1 in 100	Talk to your doctor immediately if any of your skin becomes red, swollen or sore to touch.
Low blood calcium levels	Less than 1 in 1,000	You should have regular blood tests to check your calcium levels. Tell your doctor immediately if you have: • numbness or tingling in your fingers, toes or around your mouth • muscle stiffness, spasms, twitches or cramps.

Rare health risks:

Atypical (unusual) thigh bone fracture	Less than 1 in 1,000	This is a rare type of thigh bone fracture that can occasionally happen after many years of treatment, even with little or no force. Talk to your doctor if you have unexplained pain in your thigh, groin or hip that does not go away.
Osteonecrosis of the jaw	Less than 1 in 1,000	This is a rare problem where healing inside the mouth is delayed, usually after major dental treatment. The general advice is to maintain good oral hygiene and have regular dental check-ups.

For more information on these rare conditions, read our fact sheets, '**Atypical (unusual) thigh bone fractures**' and '**Osteonecrosis of the jaw (ONJ)**', or visit our website at **theros.org.uk/info**

Making a decision about treatment

Some people worry about starting a new drug treatment and find it hard to make a decision. You might be concerned about possible side effects or health risks, or wonder if you really need treatment. Or you might not like taking medication in general.

It's important to learn all you can about your treatment options, so you can decide what's right for you. Talk to your doctor so that you fully understand your situation. Make sure you read – and understand – any information they give you, as well as the leaflet that comes with the treatment.

No-one can make you have treatment if you don't want it. But do take the time to understand the benefits and possible risks – both of taking denosumab, and of **not** taking denosumab.

Take care when visiting online forums or chat groups on social media. Reading about other people's experiences can be helpful. But you may not always see a balance of views online. People are more likely to seek support for bad experiences than good ones. This can make it seem that everyone has problems with drug treatments. In reality, most people have no side effects at all.

If you do feel worried, before or during your treatment, talk to your doctor or pharmacist, or contact our specialist Helpline nurses.

Why have I been offered denosumab?

If you've been offered denosumab, this means your risk of breaking a bone is high enough that your bones would benefit from a drug treatment. For you, the benefits of having this drug are likely to outweigh any possible risks. In other words, your risk of health problems if you do have treatment is smaller than your risk of breaking a bone if you don't have treatment.

Your doctor will have considered lots of things before recommending denosumab, including:

- how likely you are to break a bone without treatment
- whether injections are suitable for you
- other treatments that will be suitable for you – as you'll need another treatment when you stop having denosumab
- any other health problems you have
- any other medications you take
- the treatments available at your local hospital or GP surgery
- your own thoughts and feelings about treatment.

There are other treatments available for osteoporosis, but they may not all be suitable for you. For example, many treatments are tablets, which aren't suitable for everyone. Some drugs – including denosumab – are usually only available if you've already tried other drug treatments, or if other medications aren't suitable for you. And in some areas, local guidance means doctors can only prescribe certain drugs.

If you have any questions about the treatment you've been offered, speak to your doctor. They can explain why they've recommended denosumab and tell you about any other treatments that might be suitable.

Think about the advantages and disadvantages

As with any treatment, there are advantages and disadvantages to using denosumab. You should think about these when deciding whether to have denosumab, and about what's important to you.

Here are some of the main things to consider.

Advantages

- It can help to reduce your risk of broken bones, including in your hips and spine.
- It's given as an injection, which is helpful if tablets are a problem for you.
- You'll only have one injection every six months.
- It starts to work quickly and is effective for at least 10 years of use.

Disadvantages

- As with all medications, some people get side effects (see page 3).
- There are some possible health risks after several years of use, but these are rare (see page 4).
- The benefits of the drug wear off very quickly if you stop having it (see page 2).
- Some people don't like the idea of injections.
- You'll need to visit the hospital or GP surgery every six months for an injection.

What will happen if I don't have a drug treatment?

If you decide not to take a drug treatment, it is likely that your bones will get weaker over time. This means your chance of breaking a bone will increase.

Some people may never break any bones, while others may break several. Everyone's risk is different, so it's important to understand your own situation and make the decision that's right for you.

Is there a natural alternative to medication?

People often want to know if they can improve their bone strength without taking a drug treatment. The lifestyle changes listed below are all important for your bones. But if you have a high risk of broken bones, there isn't good evidence that any non-drug approaches will improve your bone strength enough to reduce the chance of breaking a bone.

More ways to look after your bones

As well as having a drug treatment, a healthy lifestyle is important for your bone health. This includes:

- a well-balanced, varied and calcium-rich diet
- safe exposure to sunlight, so that your skin makes vitamin D
- regular weight-bearing impact exercise and muscle-strengthening exercise
- not smoking
- not drinking more than the recommended levels of alcohol
- taking steps to lower your risk of falling, as falls can lead to broken bones.

Calcium and vitamin D

Getting enough calcium and vitamin D is very important for your bones. While you're having a drug treatment, your doctor may advise you to:

- aim to consume around 1,000mg of calcium a day
- take a daily 20 microgram (20µg or 800 IU) supplement of vitamin D.

This is more than the usual recommended amount, to make sure you are getting enough for your bones. Your doctor may sometimes recommend higher or lower doses, depending on your own situation.

For more information on healthy living, including our calcium and vitamin D-rich food choosers, tips for preventing falls, and our films and fact sheets on how to exercise safely for your bones, visit **theros.org.uk/healthy-bones**

Getting more information and support

We hope this fact sheet will help you feel more informed and 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, 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.

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

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