



Drug treatments for osteoporosis: Raloxifene

Raloxifene (also known as raloxifene hydrochloride) is a drug treatment for osteoporosis. It can help to strengthen bones, making them less likely to break. It is taken as a daily tablet that you swallow.

Because of the way it works, raloxifene will only be an option if you're a woman and have been through the menopause. It's only given to women who have already broken a bone due to osteoporosis and are at risk of breaking another. It'll probably be an option only 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 been through the menopause and have broken a bone due to osteoporosis
- want to know how raloxifene can help to lower your risk of fractures (broken bones)
- want to understand the advantages and disadvantages of raloxifene, including the possible side effects.

It includes the following information:

- What is raloxifene?
- Why do I need a drug treatment?
- What does raloxifene do and how does it work?
- Who can have raloxifene?
- How do I take raloxifene?
- How will my treatment be monitored?
- What are the possible side effects?
- Making a decision about treatment
- More ways to look after your bones
- Getting more information and support

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 raloxifene?

Raloxifene is a drug treatment for osteoporosis. It is a type of medicine called a selective estrogen receptor modulator (SERM).

Why do I need a drug treatment?

Doctors follow guidelines when deciding whether to offer treatments. If your doctor has recommended raloxifene, it means your risk of breaking a bone is high enough to need a drug treatment. Raloxifene can help to strengthen and protect your bones, prevent further bone loss, and lower your risk of another broken bone.

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

What does raloxifene do and how does it work?

Raloxifene can help to make your bones stronger and reduce your risk of broken bones, particularly in your spine.

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.

Around the time of a woman's menopause, her level of the female sex hormone oestrogen decreases. Oestrogen helps to keep bones strong, so this decrease in the level of oestrogen causes the bones to get weaker.

Raloxifene is not oestrogen, but it acts like or 'mimics' oestrogen inside your bones. This can slow the breakdown of bone and help to keep your bones strong.

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

Raloxifene 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/pain

Who can have raloxifene?

Raloxifene may be suitable if you have been through the menopause and have already broken a bone because of osteoporosis. It will usually only be an option if you've already tried a standard drug treatment for your bones, or if other drugs aren't suitable for you.

When is raloxifene not suitable?

Raloxifene will not be suitable if you:

- are a man
- are a woman who has not yet been through the menopause
- have severe liver or kidney problems
- have ever had a blood clot
- are pregnant or breast-feeding
- have unexplained bleeding from your vagina.

There are some other situations where raloxifene may not be suitable. Your doctor should discuss your own personal risks and benefits with you, to help decide if raloxifene is the right treatment for you.

For example, raloxifene may not be the best treatment option if:

- you are at risk of developing blood clots – because taking raloxifene could add to this risk
- you have had, or are at risk of having, a stroke – because while raloxifene does not increase the risk of having a stroke, people who have a stroke while taking the drug may be more severely affected
- you have breast cancer – you won't be able to start raloxifene until you've finished having cancer treatment, so a different osteoporosis drug treatment will probably be more suitable
- you have a high risk of breaking a hip – because it isn't clear if raloxifene reduces the risk of hip fractures as much as other drugs.

No link between raloxifene and a higher risk of breast or womb cancer

Some types of hormone replacement therapy (HRT) that contain oestrogen are linked with a small increase in the risk of breast or endometrial (womb lining) cancer.

Raloxifene is not HRT and does not contain oestrogen. It acts like oestrogen inside your bones, but it does not harm breast or womb tissue.

This means that taking raloxifene will not increase your risk of developing breast or endometrial cancer. In fact, raloxifene can help to lower the risk of certain types of breast cancer that are fuelled by oestrogen.

However, raloxifene won't be an option if you currently have – or might have – breast or endometrial cancer. This is because it isn't clear whether it is safe to take raloxifene while you're having treatment for these types of cancer.

How do I take raloxifene?

You'll take one tablet (60mg) each day. Swallow the tablet whole, with a glass of water. You can take it at any time of the day, with or without food.

If you miss a tablet

If you occasionally miss a tablet, this probably won't affect your bone health in the long term. But try to avoid this if you can. If you often forget your medication, talk to your doctor. They may be able to suggest a more suitable medication.

How will my treatment be monitored?

You won't need regular appointments while you're taking raloxifene. Your doctor probably won't need to see you again, unless you ask for an appointment to discuss your medication or general bone health.

Do speak to a doctor or pharmacist if you have any problems with your treatment. They may be able to suggest ways to help manage any side effects (see below). You should also contact them if you're struggling to take your tablets regularly.

If you break a bone while having raloxifene, 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.

Unlike some other osteoporosis drug treatments, there's no maximum length of time that you can stay on raloxifene. It's common to keep taking it for several years. But you should still have a formal treatment review after about five years.

At this review, your doctor will check if you still need a drug treatment, and that raloxifene 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 raloxifene.

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

After your review, your doctor may advise you to:

- stay on raloxifene
- start a different drug treatment instead of raloxifene
- stop having any treatment.

Your doctor can advise you on what's best for you, based on your own situation.

What are the possible side effects?

As with any drug, raloxifene can sometimes cause side effects. The most common side effects are listed on page 4.

It is important to remember that in general, side effects are less common than many people think. Most people on raloxifene 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 tablets. 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 taking raloxifene, 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 raloxifene:

The following table has information on the main side effects and how common they are. For example, at least 1 person in every 10 people who take raloxifene will get hot flushes. Up to 9 in every 10 people who use the drug will not have this problem.

Side effect	How common is it?	What can I do about it?
Hot flushes	At least 1 in 10	<p>Hot flushes are most common in the first six months of treatment. They are very unlikely to develop after this.</p> <p>You may want to try cool, cotton clothes and bed sheets, using a hand fan, and drinking plenty of cold water.</p> <p>If you already get hot flushes because of the menopause, talk to your doctor or nurse about ways to manage them.</p>
Nausea (feeling sick), vomiting (being sick) or pain in your abdomen (tummy)	At least 1 in 10	
Flu-like symptoms (such as fever, chills, muscle or joint pain, headache)	At least 1 in 10	Speak to your doctor if you think raloxifene is causing any of these problems. They can talk to you about ways to manage them.
Leg cramps	Less than 1 in 10	
Swollen hands, feet and ankles	Less than 1 in 10	

Uncommon health risks:

Deep vein thrombosis (blood clot in a vein)	Less than 1 in 100	<p>Your risk of this will be higher if you've had a blood clot before or are unable to move about.</p> <p>If you're about to have an operation or your mobility has become worse, speak to your GP. You will probably need to stop taking raloxifene until you are better.</p> <p>If you're planning a flight or other journey lasting more than five hours, it's a good idea to do exercises and wear flight socks to reduce the risk of clots.</p> <p>A blood clot in a vein can be dangerous. If you develop signs such as throbbing pain, cramp, heavy ache or swelling in the affected area, get medical advice straight away.</p>
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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 raloxifene, and of **not** taking raloxifene.

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 raloxifene?

If you've been offered raloxifene, 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 taking 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 raloxifene, including:

- how likely you are to break a bone without treatment
- whether tablets are suitable for you
- 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, some treatments involve going to a hospital for injections or a 'drip' in your arm, which may not be convenient for everyone. Some drugs – including raloxifene – are usually only available if you've already tried other drug treatments, or if other drugs 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 raloxifene, 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 taking raloxifene. You should think about these when deciding whether to have raloxifene, 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, particularly in your spine.
- You can take the tablet at any time of day, with or without food. Many people find this easier than other osteoporosis drug treatments.

Disadvantages

- As with all medications, some people get side effects (see page 3).
- Daily tablets aren't suitable for everyone.

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 on page 6 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 taking medication, 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 our website at theros.org.uk/healthy-bones

Getting more information and support

We hope this fact sheet will help you feel more prepared 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

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 theros.org.uk/info

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