

Drug treatments for osteoporosis: Raloxifene (Evista)

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 raloxifene?

Raloxifene is used to reduce the risk of broken bones in women with osteoporosis. It is taken as a daily tablet, swallowed whole at any time, with or without food.

Raloxifene is a member of a group of drug treatments called Selective Estrogen Receptor Modulators (SERMs). Although not hormones, SERMs mimic the action of the hormone oestrogen on certain organs or tissues in the body while at the same time blocking the effect of oestrogen in others. At present, raloxifene is the only SERM used to treat osteoporosis. Raloxifene mimics the positive effects of oestrogen on bone tissue helping to keep bone strong but does not affect breast or womb tissue. This means that long-term use of raloxifene does not carry the increased risk of cancer of the lining of the womb (endometrial cancer) or breast cancer that is associated with long term use of oestrogen based hormone replacement therapy (HRT).

Why do I need a drug treatment for osteoporosis and how does raloxifene 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 worn away than is rebuilt osteoporosis occurs. Raloxifene is known as an antiresorptive drug, which inhibits the cells that wear down bone (osteoclasts) and as a consequence improve bone strength.

Which products contain raloxifene?

Evista*

Dose	60mg daily tablet
Licensing details	F S

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 glucocorticoid ("steroid") medication

* A generic (non-branded) form of raloxifene is also available.

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.

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. Reduce the risk of side effects and what can be done to reduce them

As with any drug, there are potential side effects with raloxifene. 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 the 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 raloxifene. So some common conditions 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 raloxifene if they were seen in more patients treated with raloxifene than with placebo. The symptoms below are those that can be thought of as “true side effects”.

All drug treatments can cause side effects.

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.

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. 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 does raloxifene cause?

Potential side effects	How common is it?	What can I do to reduce the risk of this occurring?
Hot flushes	24 in 100 in the treatment group compared to 18 in 100 in the placebo group	Raloxifene can cause menopausal symptoms so is not generally recommended if you are experiencing them already.
Swollen hands, feet and ankles (peripheral oedema)	14 in 100 in the treatment group compared to 12 in 100 in the placebo group	If you experience continuing problems that you think may be caused by your treatment, you should speak to your doctor
Flu-like symptoms	16 in 100 in the treatment group compared to 14 in 100 in placebo group	
Leg cramps	12 in 100 in treatment group compared to 8 in 100 in the placebo group	

Other health risks associated with raloxifene

Deep vein thrombosis DVT affects between 1 in 100 to 1 in 1000 users

3. Make sure raloxifene is the treatment for you

- If you have a history of breast cancer you will need to discuss with your doctor whether raloxifene is an appropriate treatment for you. Another member of the SERM family (tamoxifen) is used in the treatment of breast cancer and some research trials have shown a reduction in breast cancer risk in women at low risk who were taking raloxifene for their bones. For women with above average risk for developing breast cancer the benefit was equivalent to tamoxifen. Discuss this with your doctor. If you are taking a breast cancer drug, you are likely to be advised to wait until you finish your cancer drug before you start taking raloxifene.

- There is a slight increase in the risk of blood clots associated with raloxifene. The risk is a similar to that of hormone replacement therapy (HRT) or the contraceptive pill containing oestrogen. If you are at risk of blood clots speak to your doctor about a treatment review to make sure the medicine is appropriate for you. It may not be considered appropriate if you have had a blood clot in the past or are immobile or likely to be, e.g after an operation.
- Raloxifene can increase certain fatty acids in the blood, which can increase the risk of developing heart disease (specifically serum triglycerides). If you already have known raised levels of triglycerides in the blood, your doctor will want to check your levels with regular blood tests if you are taking raloxifene.
- Raloxifene will not be recommended if you are of childbearing age or if you are breast feeding.
- Because it is broken down in the liver it is not generally recommended if you have liver disease.

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

Raloxifene is generally prescribed long term so you need to be happy with the treatment. Although it is important that you take the treatment 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.

Although there is no formal guidance about how long you should take raloxifene it is considered good practice for your doctor to review your treatment after a few years.

At this review your doctor will make sure that the drugs are still needed and that they aren't causing sideeffects. Your doctor will be able to advise you on what is best for you based on your individual circumstances.

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

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.

For further information on drug treatments for osteoporosis, such as how to decide which drug to take, see our booklet *All about Osteoporosis*. Fact sheets are available on each osteoporosis drug.

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**

