

Package leaflet: Information for the patient**Raloxifene Hydrochloride 60mg
Film-coated tablets****Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
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1. What this medicine is and what it is used for

The name of your medicine is Raloxifene 60 mg film-coated tablets and contains the active ingredient raloxifene hydrochloride. Raloxifene belongs to a group of non-hormonal medicines called Selective Oestrogen Receptor Modulators (SERMs). When a woman reaches the menopause, the level of the female sex hormone oestrogen goes down. Raloxifene mimics some of the helpful effects of oestrogen after the menopause.

This medicine is used to treat and prevent osteoporosis in postmenopausal women. It reduces the risk of vertebral fractures in women with postmenopausal osteoporosis. A reduction in the risk of hip fractures has not been shown.

Osteoporosis is a disease that causes your bones to become thin and fragile - this disease is especially common in women after the menopause. Although it may have no symptoms at first, osteoporosis makes you more likely to break bones, especially in your spine, hips and wrists and may cause back pain, loss of height and a curved back.

2. What you need to know before you take this medicine**Do not take this medicine**

- If you are allergic to raloxifene or any of the other ingredients of this medicine (listed in section 6)
- If there is still a possibility that you can get pregnant, raloxifene could harm your unborn child.
- If you are being treated or have been treated for blood clots in the legs (deep vein thrombosis, in the lungs (pulmonary embolism) or in the eyes (retinal vein thrombosis).
- If you have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestatic jaundice).
- If you have any unexplained vaginal bleeding. This must be investigated by your doctor.
- If you have active uterine cancer, as there is insufficient experience of raloxifene use in women with this disease.
- If you have severe kidney problems.

Warnings and precautions

The following are reasons why this product may not be suitable for you.

If any of them apply to you, talk to your doctor before you take the medicine.

- If you are immobilised for some time such as being wheelchair bound, needing to be admitted to a hospital or having to stay in bed while recovering from an operation or an unexpected illness as these may increase your risk of blood clots (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis).
- If you have liver disease
- If you are receiving oral oestrogen therapy.
- If you are suffering from breast cancer, as there is insufficient experience of Raloxifene use in women with this disease.
- If you have had a cerebrovascular accident (e.g. stroke), or if your doctor has told you that you are at high risk of having one.

It is unlikely that this medicine will cause vaginal bleeding. So any vaginal bleeding while you take this medicine is unexpected. You should have this investigated by your doctor.

This medicine does not treat postmenopausal symptoms, such as hot flushes.

This medicine lowers total cholesterol and LDL (“bad”) cholesterol. In general, it does not change triglycerides or HDL (“good”) cholesterol.

However, if you have taken oestrogen in the past and had extreme elevations in triglycerides, you should talk to your doctor before taking this medicine.

Other medicines and Raloxifene

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking digitalis medicines for your heart or anticoagulants like warfarin to thin your blood, your doctor may need to adjust your dose of these medicines.

Tell your doctor if you are taking cholestyramine which is mainly used as lipid-lowering medicine, because Raloxifene may not work as well.

Pregnancy, breast-feeding and fertility

This medicine is for use only by postmenopausal women and must not be taken by women who could still have a baby. Raloxifene could harm your unborn child.

Do not take this medicine if you are breast-feeding as it might be excreted in mother’s milk.

Driving and using machines

This medicine has no or negligible effects on driving or using machines.

3. How to take this medicine

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose is one tablet a day. It does not matter what time of day you take your tablet but taking the tablet at the same time each day will help you remember to take it. You may take it with or without food.

The tablets are for oral use. Swallow the tablet whole. If you wish you may take a glass of water with it. Do not break or crush the tablet before taking it. A broken or crushed tablet may taste bad and there is a possibility that you will receive an incorrect dose.

Your doctor will tell you how long you should continue to take raloxifene. The doctor may also advise you to take calcium and vitamin D supplements.

If you take more of this medicine than you should

Tell your doctor or pharmacist. If you take more of this medicine than you should, you could have leg cramps and dizziness.

If you forget to take this medicine

Take a tablet as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten tablet dose.

If you stop taking this medicine

You should talk to your doctor first.

It is important that you continue taking this medicine for as long as your doctor prescribes the medicine.

This medicine can treat or prevent your osteoporosis only if you continue to take the tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The majority of side effects seen with this medicine have been mild.

Very common side effects (affects more than 1 user in 10):

- Hot flushes (vasodilatation)
- Flu syndrome
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain and stomach upset
- Increased blood pressure

Common side effects (affects 1 to 10 users in 100):

- Headache including migraine
- Leg cramps
- Swelling of hands, feet and legs (peripheral oedema)
- Gallstones

- Rash
- Mild breast symptoms such as pain, enlargement and tenderness

Uncommon side effects (affects 1 to 10 users in 1000):

- Increased risk of blood clots in the legs (deep vein thrombosis)
- Increased risk of blood clots in the lungs (pulmonary embolism)
- Increased risk of blood clots in the eyes (retinal vein thrombosis)
- Skin around the vein is red and painful (superficial vein thrombophlebitis)
- Blood clot in an artery (for example stroke, including an increased risk of dying from stroke)
- Decrease in the number of the platelets in the blood

In rare cases, blood levels of liver enzymes may increase during treatment with this medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after (EXP). The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household

waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What this medicine contains

- Each film-coated tablet contains 60 mg of Raloxifene Hydrochloride equivalent to 56 mg Raloxifene.
- The other ingredients are

Tablet core:

Povidone K 30, Polysorbate 80, Glycine, Crospovidone, Microcrystalline cellulose, Silica colloidal anhydrous, Magnesium stearate.

Tablet coat:

Opadry white (contains Polysorbate 80, Carnauba wax, Polyethylene glycol, Hypromellose and Titanium dioxide (E171)).

What this medicine looks like and contents of the pack

- These tablets are white to off-white, oval biconvex film-coated tablets plain on one side and '60' on other side
- The tablets are available in blister packs of 14, 28 or 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Raloxifene Hydrochloride 60mg Film-Coated Tablets; PL 17907/0399

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