Package leaflet: Information for the user

Raloxifene Hydrochloride 60 mg Film-coated Tablets
raloxifene hydrochloride

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 Raloxifene Hydrochloride is and what it is used for

Raloxifene Hydrochloride contains the active substance raloxifene hydrochloride.

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

How Raloxifene Hydrochloride works

Raloxifene Hydrochloride 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 Hydrochloride mimics some of the helpful effects of oestrogen after the menopause.

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 Raloxifene Hydrochloride

Do not take Raloxifene Hydrochloride:

- If you are allergic to raloxifene or any of the other ingredients of this medicine (listed in section 6).
- 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 there is still a possibility that you can get pregnant, Raloxifene Hydrochloride could harm your unborn child.
- If you have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestatic jaundice).

- If you have severe kidney problems
- 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 Hydrochloride use in women with this disease.

Warnings and precautions
Talk to your doctor or pharmacist before taking Raloxifene Hydrochloride

- If you are immobilised for some time such as being wheel-chair 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 had a cerebrovascular accident (e.g. stroke), or if your doctor has told you that you are at high risk of having one.
- If you have liver disease
- If you are suffering from breast cancer, as there is insufficient experience of Raloxifene Hydrochloride use in women with this disease.
- If you are receiving oral oestrogen therapy.

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

Raloxifene Hydrochloride does not treat postmenopausal symptoms, such as hot flushes.

Raloxifene Hydrochloride 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 Raloxifene Hydrochloride.

Raloxifene Hydrochloride contains lactose
If you have been told by your doctor that you have an intolerance to lactose, a type of sugar, contact your doctor before taking this medicinal product.

Other medicines and Raloxifene Hydrochloride
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
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 Hydrochloride may not work as well.

Pregnancy and breast-feeding
Raloxifene Hydrochloride is for use only by postmenopausal women and must not be taken by women who could still have a baby. Raloxifene Hydrochloride could harm your unborn child.
Do not take Raloxifene Hydrochloride if you are breast-feeding as it might be excreted in mother's milk.

Driving and using machines
Raloxifene Hydrochloride has no or negligible effects on driving or using machines.

3. How to take Raloxifene Hydrochloride

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 Hydrochloride. The doctor may also advise you to take calcium and vitamin D supplements.

If you take more Raloxifene Hydrochloride than you should
Tell your doctor or pharmacist. If you take more Raloxifene Hydrochloride than you should you could have leg cramps and dizziness.

If you forget to take Raloxifene Hydrochloride
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 Raloxifene Hydrochloride
You should talk to your doctor first.
It is important that you continue taking Raloxifene Hydrochloride for as long as your doctor prescribes the medicine, Raloxifene Hydrochloride 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 Raloxifene Hydrochloride have been mild.

Very common: may affect more than 1 in 10 people
- Hot flushes (vasodilatation)
- Flu syndrome
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain and stomach upset
- Increased blood pressure

Common: may affect up to 1 in 10 people
- 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: may affect up to 1 in 100 people

- 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 Raloxifene Hydrochloride.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Raloxifene Hydrochloride

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 and blister 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 Raloxifene Hydrochloride contains

- The active substance is raloxifene hydrochloride. Each tablet contains 60 mg of raloxifene hydrochloride, which is equivalent to 56 mg raloxifene.

- The other ingredients are:

Tablet core: Sodium starch glycolate (primogel) type A, citric acid monohydrate, microcrystalline cellulose, dibasic calcium phosphate 2-hydrate, poloxamer 407, magnesium stearate.

Tablet coating: Titanium dioxide ***E171***, lactose monohydrate, hypromellose 2910/ hypromellose 15cP ***E464***, macrogol 4000, hypromellose 2910/ hypromellose 3cP ***E464***, hypromellose 2910/ hypromellose 50cP ***E464***.

What Raloxifene Hydrochloride looks like and contents of the pack

Elliptically shaped (12.6 mm x 6.6 mm), white film-coated tablets. They are packed in blisters in boxes of 14, 28, 30, and 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Actavis Group PTC ehf.
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

Manufacturers
Pharmathen S.A.
Dervenakion 6
Pallini 15351
Attiki
Greece

And

Pharmathen International S.A.
Industrial Park Sapes,
Rodopi Prefecture, Block No 5,
Rodopi 69300,
Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Raloxifene Hydrochloride 60 mg Film-coated Tablets
Ireland	Raloxifene Hydrochloride 60 mg Film-coated Tablets

This leaflet was last revised in December 2018