Osteoporosis is a disease that causes your bones to become thin and fragile - this disease is especially common in postmenopausal women. Raloxifene hydrochloride is used to treat and prevent osteoporosis in postmenopausal women. Raloxifene hydrochloride may weaken your bones, especially in your spine, hips, and wrists and may cause back pain, loss of height, and a curved back. Raloxifene hydrochloride mimics some of the helpful effects of estrogen after the menopause.

What is Raloxifene hydrochloride used for and what does it do?

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 estrogen goes down. Raloxifene hydrochloride mimics some of the helpful effects of estrogen 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.

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 is unexpected. You should have this investigated by your doctor.

If you are allergic to raloxifene or any of the ingredients of this medicine (listed in section 6).

• 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.

If you have severe kidney problems.

Fasting Precautions

Talk to your doctor or pharmacist before you take Raloxifene hydrochloride.

• If you have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestasis 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 hydrochloride use in women with this disease.

• If you have severe kidney problems.

Warnings and precautions

Do not take Raloxifene hydrochloride:

• If you are suffering from breast cancer, as there is insufficient experience of Raloxifene hydrochloride use in women with this disease.

• If you have 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.

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 estrogen in the past and had extreme elevations in triglycerides, you should talk to your doctor before taking Raloxifene hydrochloride.

Other medicines and Raloxifene hydrochloride

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

Talk to your doctor if you are taking cholestyramine which is mainly used as lipid-lowering medicine.

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 - it may be excreted in mother’s milk.

Driving and using machines

Raloxifene hydrochloride has no known effects on driving or using machines.

Raloxifene hydrochloride tablets contain 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.

3. HOW TO TAKE RALOXIFENE HYDROCHLORIDE

Always take this medicine exactly as your doctor has told you. 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 to 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.

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 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.

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 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.

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 have been:

Very common (may affect more than 1 in 10 people):

• Hot flashes (vasodilation)

• 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 the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RALOXIFENE HYDROCHLORIDE

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Keep the blister in the outer carton in order to protect from light and moisture. Do not freeze.

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

2. What you need to know before you take Raloxifene hydrochloride

3. How to take Raloxifene hydrochloride

4. Possible side effects

5. How to store Raloxifene hydrochloride

6. Contents of the pack and other information

What Raloxifene hydrochloride tablets contain

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

The other ingredients of Raloxifene hydrochloride tablets are:

Tablet core: Sodium starch glycylate, citric acid monohydrate, microcrystalline cellulose, dibasic calcium phosphate, povidone 40T, magnesium stearate

Tablet coating: Hypromellose, lactose monohydrate, polyethylene glycol, titanium dioxide (E171) and macrogol/PEG 400.

What Raloxifene hydrochloride tablets look like and contents of the pack

Raloxifene hydrochloride are white elliptical, film-coated tablets. They are packed in blisters. The blister boxes contain 14, 28, 30, 84, or 90 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pharmathen S.A.
6, Dervenakion Str., 153 51
Pallini, Attiki
Greece
Tel: +30 210 66 65 067
Fax: +30 210 66 65 749
Email info@pharmathen.com

Distributed by

Dr. Reddy’s Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD, United Kingdom

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