

Medication Guide

Raloxifene Hydrochloride Tablets, USP for Oral Use (ral-ox-i-fene)

Read the Medication Guide that comes with raloxifene hydrochloride tablets before you start taking it and each time you refill your prescription. The information may have changed. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. Talk with your doctor about raloxifene hydrochloride tablets when you start taking it and at regular checkups.

What is the most important information I should know about raloxifene hydrochloride tablets?

Serious and life-threatening side effects can occur while taking raloxifene hydrochloride tablets. These include blood clots and dying from stroke:

- Increased risk of blood clots in the legs (deep vein thrombosis) and lungs (pulmonary embolism) have been reported with raloxifene hydrochloride tablets. Women who have or have had blood clots in the legs, lungs, or eyes should not take raloxifene hydrochloride tablets.
 - Women who have had a heart attack or are at risk for a heart attack may have an increased risk of dying from stroke when taking raloxifene hydrochloride tablets.
1. Before starting raloxifene hydrochloride tablets, tell your doctor if you have had blood clots in your legs, lungs, or eyes, a stroke, mini-stroke (transient ischemic attack), or have an irregular heartbeat.
 2. Stop taking raloxifene hydrochloride tablets and call your doctor if you have:
 - leg pain or a feeling of warmth in the lower leg (calf).
 - swelling of the legs, hands, or feet.
 - sudden chest pain, shortness of breath, or coughing up blood.
 - sudden change in your vision, such as loss of vision or blurred vision.
 3. Being still for a long time (such as sitting still during a long car or airplane trip or being in bed after surgery) can increase your risk of blood clots. (See “What should I avoid if I am taking raloxifene hydrochloride tablets?”)

What are raloxifene hydrochloride tablets?

Raloxifene hydrochloride tablets are a type of prescription medicine called a Selective Estrogen Receptor Modulator (SERM). Raloxifene hydrochloride tablets are for women after menopause, and has more than one use:

- Osteoporosis: Raloxifene hydrochloride tablets treat osteoporosis by helping make your bones stronger and less likely to break.
- Invasive Breast Cancer: If you have osteoporosis or are at high risk for breast cancer, raloxifene hydrochloride can be used to lower your chance of getting invasive breast cancer. Raloxifene hydrochloride will not totally get rid of your chance of getting breast cancer. Your doctor can estimate your risk of breast cancer by asking you about risk factors, including:
 - your age (getting older).
 - family history of breast cancer in your mother, sister, or daughter
 - a history of any breast biopsy, especially an abnormal biopsy.

You and your doctor should talk about whether the possible benefit of raloxifene hydrochloride in lowering your chance of getting invasive breast cancer is greater than its possible risks.

Raloxifene hydrochloride tablets are not for use in premenopausal

women (women who have not passed menopause).

Who should not take raloxifene hydrochloride tablets?

Do not take raloxifene hydrochloride tablets if you:

- have or have had blood clots in your legs, lungs, or eyes. Taking raloxifene hydrochloride tablets may increase the risk of getting blood clots.
- are pregnant or could become pregnant. Raloxifene hydrochloride tablets could harm your unborn child.
- are nursing a baby. It is not known if raloxifene hydrochloride tablets passes into breast milk or what effect it might have on the baby.

What should I tell my doctor before taking raloxifene hydrochloride tablets?

Raloxifene hydrochloride tablets may not be right for you. Before taking raloxifene hydrochloride tablets, tell your doctor about all your medical conditions, including if you:

- have had blood clots in your legs, lungs, or eyes, a stroke, mini-stroke (TIA/transient ischemic attack), or a type of irregular heartbeat (atrial fibrillation).
- have had breast cancer. Raloxifene hydrochloride tablets have not been fully studied in women who have a history of breast cancer.
- have liver or kidney problems.
- have taken estrogen in the past and had a high increase of triglycerides (a kind of fat in the blood).
- are pregnant, planning to become pregnant, or breast-feeding (see “Who should not take raloxifene hydrochloride tablets?”).

Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine. Especially tell your doctor if you take*:

- warfarin (Coumadin®, Jantoven®)
If you are taking warfarin or other coumarin blood thinners, your doctor may need to do a blood test when you first start or if you need to stop taking raloxifene hydrochloride tablets. Names for this test include “prothrombin time,” “pro-time,” or “INR.” Your doctor may need to adjust the dose of your warfarin or other coumarin blood thinner.
- cholestyramine
- estrogens

Raloxifene hydrochloride tablets should not be taken with cholestyramine or estrogens.

How should I take raloxifene hydrochloride tablets?

- Take raloxifene hydrochloride tablets exactly how your doctor tells you to.
- Keep taking raloxifene hydrochloride tablets for as long as your doctor prescribes it for you. It is not known how long you should keep taking raloxifene hydrochloride to lower your chance of getting invasive breast cancers.
- It is important to get your refills on time so you do not run out of the medicine.
- Take one raloxifene hydrochloride tablet each day.
- Take raloxifene hydrochloride tablets at any time of the day, with or without food.
- To help you remember to take raloxifene hydrochloride tablets, it may be best to take it at about the same time each day.

- Calcium and vitamin D may be taken at the same time as raloxifene hydrochloride tablets. It is important to take calcium and vitamin D, as directed by your physician to treat osteoporosis.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose. Do not take two doses at the same time.

What should I avoid while taking raloxifene hydrochloride tablets?

- Being still for a long time (such as during long trips or being in bed after surgery) can increase the risk of blood clots. Raloxifene hydrochloride tablets may add to this risk. If you will need to be still for a long time, talk with your doctor about ways to reduce the risk of blood clots. On long trips, move around periodically. Stop taking raloxifene hydrochloride tablets at least 3 days before a planned surgery or before you plan on being still for a long time. You should start taking raloxifene hydrochloride tablets again when you return to your normal activities.
- Some medicines should not be taken with raloxifene hydrochloride tablets (see “What should I tell my doctor before taking raloxifene hydrochloride tablets?”).

What are the possible side effects of raloxifene hydrochloride tablets?

Serious and life-threatening side effects can occur while taking raloxifene hydrochloride tablets. These include blood clots and dying from stroke:

- Increased risk of blood clots in the legs (deep vein thrombosis) and lungs (pulmonary embolism) have been reported with raloxifene hydrochloride tablets. Women who have or have had blood clots in the legs, lungs, or eyes should not take raloxifene hydrochloride tablets.
- Women who have had a heart attack or are at risk for a heart attack may have an increased risk of dying from stroke when taking raloxifene hydrochloride tablets.

See “What is the most important information I should know about raloxifene hydrochloride tablets?”

The most common side effects of raloxifene hydrochloride tablets are hot flashes, leg cramps, swelling of the feet, ankles, and legs, flu syndrome, joint pain, and sweating. Hot flashes are more common during the first 6 months after starting treatment.

These are not all the side effects of raloxifene hydrochloride tablets. Tell your doctor about any side effect that bothers you or that does not go away. If you have any problems or questions that concern you while taking raloxifene hydrochloride tablets, ask your doctor or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to Exelan Pharmaceuticals, Inc. at 1-866-604-3268 or FDA at 1-800-FDA-1088.

What else should I know about raloxifene hydrochloride tablets?

- Do not use raloxifene hydrochloride tablets to prevent heart disease, heart attack, or strokes.
- To get the calcium and vitamin D you need, your doctor may advise you to change your diet and/or take supplemental calcium and vitamin D. Your doctor may suggest other ways to help treat osteoporosis, in addition to taking raloxifene hydrochloride tablets and getting the calcium and vitamin D you need. These may include regular exercise, stopping smoking, and drinking less alcohol.
- Women who have hot flashes can take raloxifene hydrochloride

tablets. Raloxifene hydrochloride tablets do not treat hot flashes, and it may cause hot flashes in some women. (See “What are the possible side effects of raloxifene hydrochloride tablets?”)

- Raloxifene hydrochloride tablets have not been found to cause breast tenderness or enlargement. If you notice any changes in your breasts, call your doctor to find out the cause. Before starting and while taking raloxifene hydrochloride tablets you should have breast exams and mammograms, as directed by your doctor.
- Raloxifene hydrochloride tablets should not cause spotting or menstrual-type bleeding. If you have any vaginal bleeding, call your doctor to find out the cause. Raloxifene hydrochloride tablets have not been found to increase the risk for cancer of the lining of the uterus.
- Women in clinical trials have taken raloxifene hydrochloride tablets for up to eight years.

How should I store raloxifene hydrochloride tablets?

- Store raloxifene hydrochloride tablets at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP].
- Keep raloxifene hydrochloride tablets and all medicines out of the reach of children.

General Information about the safe and effective use of raloxifene hydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use raloxifene hydrochloride tablets for a condition for which it was not prescribed. Do not give your raloxifene hydrochloride tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide is a summary of the most important information about raloxifene hydrochloride tablets. If you would like more information about raloxifene hydrochloride tablets, talk with your doctor. You can ask your doctor or pharmacist for information about raloxifene hydrochloride tablets that is written for health professionals.

What are the ingredients in raloxifene hydrochloride tablets?

Active Ingredient: raloxifene hydrochloride

Inactive Ingredients: mannitol, crospovidone, hydroxypropyl cellulose, poloxamer 407, magnesium stearate and opadry white (titanium Dioxide, hypromellose 2910 (3cP), hypromellose 2910 (6cP), macrogol/PEG 400 and polysorbate 80).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

*All brand names mentioned are trademark of their respective owners and are not of Exelan Pharmaceuticals, Inc.

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