PART III: CONSUMER INFORMATION

[Pr]RALOXIFENE
Raloxifene Hydrochloride Tablets

This leaflet is part III of a three-part "Product Monograph" published when RALOXIFENE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RALOXIFENE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What RALOXIFENE is used for:
RALOXIFENE is used to treat or to prevent osteoporosis in postmenopausal women.

What is Osteoporosis?
Osteoporosis is a thinning and weakening of the bones making the bones more likely to break. It is common in women after menopause or after removal of the ovaries because of the decrease in estrogens. A variety of risk factors may promote osteoporosis. These include:

- Caucasian or Asian descent
- Slender build
- Early menopause
- Smoking
- Drinking alcohol
- A diet low in calcium
- Lack of exercise
- A family history of osteoporosis

The greater the number of risk factors, the greater the probability of developing osteoporosis.

Initially osteoporosis usually does not cause any symptoms, but if left untreated may result in fractures. While most fractures are painful, fractures of the spine may not be noticed until they result in loss of height or a stooped posture. The fractures may occur as the result of normal every day activity or from minor injuries, which would ordinarily not result in broken bone.

How can osteoporosis be prevented or treated?
- Eat a balanced diet. Vitamin D and calcium are necessary for building strong bones. The requirement for vitamin D increases as you grow older. In the winter, when there is less sunlight, your skin produces less vitamin D. Discuss with your doctor the need to take vitamin D and calcium supplements.
- Do not smoke.
- Exercise. Bones need exercise to stay strong and healthy. Consult your doctor about an exercise program suitable to you.
- While diet, exercise and vitamins are essential to good health, they may not be enough to offset the effects of estrogen decline in some women's bodies after menopause. Consequently, some people may require medications such as RALOXIFENE to prevent or treat osteoporosis.

What RALOXIFENE does:
RALOXIFENE is a Selective Estrogen Receptor Modulator or SERM. RALOXIFENE is not a hormone, but it acts like estrogen in some parts of your body including the bones, but not like estrogen in other parts of the body. In the bones it promotes the building of new bone, either to prevent or treat osteoporosis.

When RALOXIFENE should not be used:
Do not take RALOXIFENE if:
- you have **not** passed menopause. RALOXIFENE is for use only by women **after menopause.**
- **you are pregnant or could become pregnant. RALOXIFENE could harm your unborn child.**
- **you are nursing a baby. It is not known if RALOXIFENE passes into breast milk or what effect it might have on the baby.**
- you have or have had blood clots in the veins that required a doctor's treatment. This may include clots in the legs, lungs or eyes. Taking RALOXIFENE may increase the risk of getting these blood clots.
- you are allergic to raloxifene or any of the other ingredients in RALOXIFENE listed in the "nonmedicinal ingredients" section below.

What the medicinal ingredient is:
raloxifene hydrochloride

What the important nonmedicinal ingredients are:
citric acid, dibasic calcium phosphate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407, polyethylene glycol, sodium starch glycolate, titanium dioxide.

What dosage form RALOXIFENE comes in:
Tablet 60 mg.

WARNINGS AND PRECAUTIONS

Before starting RALOXIFENE and to get the best possible treatment, be sure to tell your doctor if you:

- are pregnant, breast feeding, still have menstrual bleeds, or have had a menstrual bleed in the last year, as RALOXIFENE is only for postmenopausal women.
- have had an allergic reaction to any medicine you have taken.
- are intolerant to lactose because RALOXIFENE contains lactose.
- have or ever had liver problems.
- have or ever had blood clots in the veins. If you take warfarin (blood thinner) or other coumarin derivatives, RALOXIFENE may not be suitable for you. RALOXIFENE is contraindicated in women with an active or past history of blood clots in the veins. If you are taking the blood thinners for other reasons your doctor may need to check your prothrombin (blood clotting) time and adjust your medicine when you first begin taking RALOXIFENE.
- are currently on any other medications, prescription or non prescription.
- have had a stroke or have a history of other significant risk factors for stroke, such as a "mini-stroke" (TIA/transient ischemic attack), or a type of irregular heartbeat (atrial fibrillation).

Being immobile for a long time can increase the risk of blood clots in the veins. RALOXIFENE may add to this risk. If while taking RALOXIFENE you plan to be immobile, such as staying in bed after surgery, or taking a long plane trip, you should stop taking

RALOXIFENE at least 3 days before, to reduce your risk of blood clots in the veins. When you are back on your feet, you may start taking RALOXIFENE again (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

INTERACTIONS WITH THIS MEDICATION

You should always tell your doctor about all drugs that you are taking or plan to take before starting to take RALOXIFENE.

The effect of RALOXIFENE is significantly reduced if taken with cholestyramine (products which contain cholestyramine include Questran®, Questran Light®, Alti-Cholestyramine Light, Novo-Cholamine, Novo-Cholamine Light, Cholestryramine). Therefore, you should not take cholestyramine while taking RALOXIFENE.

It is not recommended that you combine RALOXIFENE with hormone replacement therapy (ERT or HRT) since safety information is limited and no studies have been done to look at the effectiveness of this combination.

During clinical trials, raloxifene was taken with commonly prescribed medications such as acetaminophen, digoxin, nonsteroidal anti-inflammatory drugs (NSAIDS), and oral antibiotics with no observed problems. However, because each patient is different, you should always check with your doctor before taking any other medication.

PROPER USE OF THIS MEDICATION

Usual dose:
Take one RALOXIFENE 60 mg tablet, once-a-day, any time, with or without food. RALOXIFENE comes in a bottle with 100 tablets and a 30-day blister pack that you start as soon as you fill your prescription. Each day of the week is printed above each tablet to make it easy to check if you've taken your pill that day.

You might find it helpful to take your tablet at the same time every day so that it's simply part of your routine. The efficacy of RALOXIFENE is dependent upon your taking it regularly. Therefore, you should keep taking RALOXIFENE until your doctor advises you otherwise.

Overdose:

If you take too much RALOXIFENE, immediately contact your doctor, go to your nearest hospital emergency department, or contact the Regional Poison Control Centre. Show the doctor your blister pack of tablets. Do this even if there are no signs of discomfort or poisoning.

Missed Dose:
If you miss a day of RALOXIFENE take one pill as soon as you remember and resume one tablet once daily. Do not take two doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

During clinical trials, some women did have mild side effects however most women did not find these side effects serious enough to stop taking RALOXIFENE. The most common side effects of RALOXIFENE are:

- hot flashes
- leg cramps

Another common side effect is flu-like symptoms.

Similar to estrogen replacements, RALOXIFENE may increase the risk of blood clots in the veins. Although this is an uncommon side effect, if you experience any of the following unusual symptoms talk to your doctor immediately:

- redness, swelling, heat or pain in your calves and legs
- sudden chest pain or shortness of breath
- a sudden change in your vision

RALOXIFENE is not associated with adverse effects on the uterus, breast, or mental function. Therefore, any unexplained uterine bleeding, breast enlargement, breast pain, change in mood or deterioration of mental function should be reported to your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	**Blood clots in the veins***			✓
Rare	**Blood clots in the lungs***			✓
Rare	**Stroke fatality****			

** See "**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**" for symptoms of blood clots in the veins. If you experience any of the listed symptoms talk to your doctor immediately.*
*** 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.*

This is not a complete list of side effects. For any unexpected effects while taking RALOXIFENE, contact your doctor or pharmacist.

HOW TO STORE IT

All medicines should be stored out of the reach of children.
RALOXIFENE should be stored at room temperature (between 15 to 30°C).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect .

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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