Osteya

Raloxifene HCl

Selective Estrogen Receptor Modulator

DESCRIPTION **Osteya** (raloxifene hydrochloride) is a selective estrogen receptor modulator (SERM) that belongs to the benzothiophene class of compounds.

ACTIONS Raloxifene decreases resorption of bone and reduces biochemical markers of bone turnover to the premenopausal range. These effects on bone are manifested as reductions in the serum and urine levels of bone turnover markers, decreases in bone resorption based on radiocalcium kinetics studies, increases in bone mineral density (BMD), and decreases in incidence of fractures. Raloxifene also has effects on lipid metabolism. Raloxifene decreases total and LDL cholesterol levels but does not increase triglyceride levels. It does not change total HDL cholesterol levels. Raloxifene is absorbed rapidly after oral administration. Approximately 60% of an oral dose is absorbed. The time to reach average maximum plasma concentration and bioavailability are functions of systemic interconversion and enterohepatic cycling of raloxifene and its glucuronide metabolites. Raloxifene and its metabolites are highly (95%) bound to plasma proteins. Raloxifene undergoes extensive first-pass metabolism to glucuronide conjugates. Raloxifene is primarily excreted in feces, and less than 0.2% is excreted unchanged in urine. Less than 6% of the raloxifene dose is eliminated in urine as glucuronide conjugates.

INDICATIONS **Osteya** is indicated for:
- Treatment and prevention of osteoporosis in postmenopausal women. For either osteoporosis treatment or prevention, supplemental calcium and/or vitamin D should be added to the diet if daily intake is inadequate.
- Reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis.
- Reduction in risk of invasive breast cancer in postmenopausal women at high risk for invasive breast cancer.

Important Limitations: **Osteya** is not indicated for the treatment of invasive breast cancer, reduction of the risk of recurrence of breast cancer, or reduction of risk of noninvasive breast cancer.

CONTRAINDICATIONS **Osteya** is contraindicated in lactating women or women who are or may become pregnant. **Osteya** may cause fetal harm when administered to a pregnant woman.
Osteya is contraindicated in women with active or past history of venous thromboembolic events, including deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis.
Osteya is also contraindicated in patients with known hypersensitivity to the product.

PRECAUTIONS
- Concomitant use of **Osteya** with systemic estrogens is not recommended.
- **Osteya** lowers serum total and LDL cholesterol by 6% to 11%, but does not affect serum concentrations of total HDL cholesterol or triglycerides. These effects should be taken into account in therapeutic decisions for patients who may require therapy for hyperlipidemia.
- Women with marked hypertriglyceridemia (>5.6 mmol/L or >500 mg/dL) should have serum triglycerides monitored when taking **Osteya**.
- **Osteya** has not been adequately studied in women with a prior history of breast cancer.
- Safety and efficacy have not been evaluated in men.
- **Osteya** should be discontinued at least 72 hours prior to and during prolonged immobilization (e.g., post-surgical recovery, prolonged bed rest), and patients should be advised to avoid prolonged restrictions of movement during travel because of the increased risk of venous thromboembolic events.
- **Osteya** may increase the incidence of hot flushes and is not effective in reducing hot flushes or flushes associated with estrogen deficiency. In some asymptomatic patients, hot flushes may occur upon beginning **Osteya** therapy.
- **Osteya** does not eliminate the risk of breast cancer. If an unexplained breast abnormality appears during treatment with **Osteya**, it should be investigated.
- Patients should be instructed to take supplemental calcium and/or vitamin D, if daily dietary intake is inadequate. Weight-bearing exercise should be considered along with the modification of certain behavioral factors, such as cigarette smoking, and/or alcohol consumption, if these factors exist.

Pregnancy: Pregnancy Category X -- **Osteya** should not be used in women who are or may become pregnant.
Nursing Mothers: It is not known whether raloxifene is excreted in human milk.
Women must not breast feed if they are obliged to use the product.
Use in children: Safety and effectiveness of **Osteya** in children have not been established.
Use in elderly: **Osteya** works equally well and is equally well tolerated by older and younger adult patients.
Renal Impairment: **Osteya** should be used with caution in patients with moderate or severe renal impairment.
Hepatic Impairment: **Osteya** should be used with caution in patients with hepatic impairment.

ADVERSE REACTIONS Adverse effects occurring at a frequency of >/=2.0% include flu syndrome, headache, leg cramps, chest pain, hot flushes, migraine, nausea, diarrhea, dyspepsia, vomiting, flatulence, peripheral edema, insomnia, vertigo, neuralgia, rash, sweating, uterine disorder, endometrial disorder, vaginal hemorrhage, urinary tract disorder.
Serious side effects are limited to a frequency of 0.7% and include deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis.

DOSAGE & ADMINISTRATION The recommended dosage is one 60-mg **Osteya** tablet daily which may be administered any time of day without regard to meals.
For the indications in risk of invasive breast cancer the optimal duration of treatment is not known.

DRUG INTERACTIONS
- Co-administration of cholestyramine with **Osteya** is not recommended.
- If **Osteya** is given concurrently with warfarin or other coumarin derivatives, prothrombin time should be monitored more closely when starting or stopping therapy with **Osteya**.
- Although not examined, **Osteya** might affect the protein binding of other drugs and should be used with caution with certain other highly protein-bound drugs such as diazepam, diazoxide, and lidocaine.

AVAILABILITY **Tablets**
Box of 28 film coated tablets each containing 60 mg Raloxifene HCl equivalent to 56 mg Raloxifene, Excipient q s 1 tablet.
Reg. Nº Lebanon 195265

This is a medicament
-A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
-The doctor and the pharmacist are experts in medicine, its benefits and risks.
-Do not by yourself interrupt the period of treatment prescribed for you.
-Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Pharmaline *- Lebanon*

Council of Arab Health Ministers
Union of Arab Pharmacists

Rev. 12/08 905425-B