

RALOXIFENE
60 mg TABLETS

SELECTIVE ESTROGEN RECEPTOR MODULATOR

60 mg PER TABLET

ORAL TABLETS

PRODUCT OVERVIEW

Specification	Details
Generic Name	Raloxifene 60 mg
Drug Class	Selective Estrogen Receptor Modulator
Active Ingredient	Raloxifene Hydrochloride
Administration Route	Oral Administration
Dosage Form	Tablets
Chemical Class	Benzothiophene Derivative
Primary Target	Estrogen Receptors
Clinical Status	Product and Jurisdiction Dependent

INTRODUCTION

Raloxifene hydrochloride is an orally active selective estrogen receptor modulator. Each tablet in this fictional NEXON catalog presentation contains 60 mg of raloxifene hydrochloride.

Its tissue-selective actions include estrogen-like effects on bone and antagonism of estrogen signaling in breast tissue. It is not an estrogen replacement or treatment for established breast cancer.

HISTORY

Raloxifene emerged from research into tissue-selective estrogen receptor modulators and entered clinical use in the late 1990s for prevention and treatment of postmenopausal osteoporosis.

The 60 mg oral tablet became an established pharmaceutical presentation. This displayed product is a fictional NEXON website catalog item rather than a claim regarding a specific approved medicine.

Approved indications, prescribing requirements, contraindications, legal classification, and availability depend on the jurisdiction and the exact manufactured product.

CHEMICAL STRUCTURE

Raloxifene hydrochloride is a benzothiophene-derived compound. Its hydrochloride salt has the formula C28H27NO4S·HCl and an approximate molar mass of 510.05 g/mol.

The nonsteroidal structure binds estrogen receptors and produces different responses by tissue. Tablets contain the hydrochloride salt; the labeled 60 mg refers to that salt in this presentation.

- Nonsteroidal benzothiophene framework
- Hydrochloride salt pharmaceutical form
- Selective estrogen-receptor modulation
- Tissue-dependent agonist and antagonist effects
- Oral tablet formulation

CHEMICAL PROFILE

Parameter	Information
Active Compound	Raloxifene Hydrochloride
Molecular Formula	C28H27NO4S·HCl
Molar Mass	Approximately 510.05 g/mol
Structural Class	Nonsteroidal Benzothiophene SERM
Administration	Oral
Dosage Form	Tablet
Primary Molecular Target	Estrogen Receptors
Labeled Strength	60 mg per Tablet
Clinical Status	Fictional NEXON Catalog Formulation

PHARMACOLOGY

After oral administration, raloxifene is absorbed through the gastrointestinal tract. It binds estrogen receptors and regulates transcription differently according to tissue-specific coregulators and physiological context.

In bone, it reduces resorption and helps preserve mineral density in postmenopausal women. In breast tissue, it antagonizes estrogen-responsive pathways without directly inhibiting aromatase.

Oral Raloxifene → Gastrointestinal Absorption → Estrogen Receptor Binding → Tissue-Selective Signaling

Raloxifene is not an anabolic-androgenic steroid, aromatase inhibitor, or treatment for existing invasive breast cancer. Its clinical balance must account for venous thromboembolism and stroke risk.

MECHANISM OF ACTION

The primary mechanism involves:

- Disintegration and dissolution of the oral tablet
- Gastrointestinal absorption of active raloxifene
- Estrogen-receptor binding in target tissues
- Tissue-specific coregulator recruitment
- Reduced osteoclast-driven bone resorption
- Antagonism of estrogen signaling in breast tissue
- Glucuronidation and predominantly fecal elimination

Raloxifene changes tissue response to estrogen rather than globally suppressing estrogen production. Benefits and risks differ across bone, breast, uterine, and vascular tissues.

PHARMACODYNAMICS

- Selective estrogen-receptor binding
- Reduced bone turnover and resorption
- Maintenance of postmenopausal bone density
- Antagonism of breast estrogen signaling
- Limited endometrial stimulation
- Effects on coagulation and vascular physiology
- Lipid and metabolic changes
- Secondary estrogen-responsive effects

ESTROGEN BIOSYNTHESIS

Raloxifene does not directly inhibit aromatase or estrogen biosynthesis, but may influence estrogen-responsive physiology through:

- Estrogen-receptor occupancy in bone
- Reduced estrogen signaling in breast tissue
- Tissue-specific agonist and antagonist activity
- Altered transcription of estrogen-responsive genes
- Reduced bone resorption in postmenopause
- Changes in endocrine and vascular pathways

The magnitude of response depends on adherence, menopausal status, baseline bone and vascular health, concurrent therapy, and individual physiology.

SKELETAL SYSTEM

Raloxifene has estrogen-like skeletal activity in postmenopausal women and may influence:

- Bone remodeling and turnover
- Bone mineral density
- Vertebral fracture risk
- Calcium and vitamin D balance
- Long-term skeletal integrity

Bone-health assessment remains important. Adequate calcium and vitamin D intake may be advised when dietary intake is insufficient; nonvertebral fracture benefits are not established in the same way.

CARDIOVASCULAR AND METABOLIC SYSTEM

Raloxifene may influence cardiovascular and metabolic physiology through:

- Increased venous thromboembolism risk
- Risk of fatal stroke in susceptible women
- Changes in lipid parameters
- Coagulation and vascular pathways
- Interaction with immobilization and baseline risk

The cardiovascular balance depends on prior thrombosis, coronary or stroke risk, smoking, prolonged immobility, concurrent medicines, and individual susceptibility.

REPRODUCTIVE SYSTEM

Raloxifene is intended for selected postmenopausal women and may influence:

- Breast estrogen-receptor signaling
- Bone and mineral metabolism
- Vasomotor symptoms
- Endometrial and uterine tissues
- Venous coagulation pathways
- Other estrogen-responsive tissues
- Postmenopausal endocrine physiology

Use during pregnancy or breastfeeding is contraindicated. Raloxifene is not indicated for premenopausal women and does not treat menopausal hot flashes; symptoms may worsen.

PHARMACOKINETICS

Following oral administration, raloxifene is absorbed, but extensive first-pass glucuronidation limits systemic bioavailability. Exposure depends on absorption, hepatic function, interacting substances, and individual physiology.

Raloxifene and its glucuronide conjugates undergo enterohepatic cycling. The compound is highly protein bound and is not principally metabolized through cytochrome P450 pathways.

Elimination occurs primarily through feces, with little urinary excretion. Bile-acid sequestrants can substantially reduce absorption and should not be co-administered according to labeling.

The complete pharmacokinetic profile of this fictional 60 mg tablet depends on the validated formulation and has not been established through independent product-specific clinical studies.

PHYSIOLOGICAL EFFECTS

Through tissue-selective estrogen-receptor modulation, raloxifene may influence bone turnover, postmenopausal vertebral fracture risk, estrogen-responsive breast tissue, lipid parameters, thermoregulation, coagulation, and vascular physiology.

Its effects differ from estrogen therapy because breast and uterine responses are not uniformly estrogenic, and from aromatase inhibitors because it does not globally reduce estrogen synthesis.

Inappropriate use can expose individuals to clinically significant harms, particularly venous thrombosis, pulmonary embolism, retinal vein thrombosis, and fatal stroke in susceptible populations.

CLINICAL APPLICATIONS

Approved raloxifene products are used for treatment and prevention of osteoporosis in postmenopausal women and for reduction of invasive breast cancer risk in specified postmenopausal groups.

Raloxifene does not treat existing breast cancer or prevent noninvasive breast cancer. Clinical use requires an approved product, indication and risk assessment, contraindication review, and monitoring.

The displayed 60 mg tablet is a fictional NEXON catalog item and should not be interpreted as an independently approved medicinal product.

SAFETY CONSIDERATIONS

Raloxifene exposure requires consideration of venous thromboembolism, stroke, cardiovascular, skeletal, hepatic, reproductive, vasomotor, and medication-related risks.

Important safety considerations include:

- Prior or active venous thromboembolism
- Deep vein, pulmonary, or retinal vein thrombosis
- Stroke and coronary-risk factors
- Periods of immobilization
- Pregnancy and breastfeeding status
- Postmenopausal status
- Bone health and fracture history
- Hot flashes and leg cramps
- Oral formulation tolerability
- Bile-acid sequestrant and other medication review
- The safety profile depends on indication, duration, baseline vascular and skeletal health, individual response, and concurrent therapy. Medical supervision is essential whenever raloxifene is prescribed.

Raloxifene should generally be stopped before and during prolonged immobilization under clinician direction. Unsupervised use to manipulate estrogen signaling cannot replace individualized risk assessment.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects may involve thromboembolic, cardiovascular, vasomotor, musculoskeletal, gastrointestinal, dermatological, reproductive, neurological, and psychological systems.

Endocrine and Vasomotor Effects

- Hot flashes or worsening vasomotor symptoms
- Changes in estrogen-receptor signaling
- Altered postmenopausal tissue response
- Peripheral edema

- Sweating
- Changes in comfort or sexual function

Cardiovascular and Metabolic Effects

- Deep vein thrombosis
- Pulmonary or retinal vein thrombosis
- Potentially fatal stroke in susceptible women
- Changes in lipid parameters
- Peripheral edema

Skeletal and Musculoskeletal Effects

- Leg cramps
- Arthralgia or joint discomfort
- Muscle pain or stiffness
- Bone-health changes despite treatment

Dermatological Effects

- Rash
- Pruritus
- Sweating
- Rare skin reactions
- Hypersensitivity reactions

Reproductive Effects

- Potential fetal harm
- Inappropriate use before menopause
- Vaginal bleeding requiring evaluation
- Effects on estrogen-responsive tissues
- Changes in sexual comfort

Hepatic and Neurological Effects

- Changes in liver-function parameters
- Possible altered exposure in liver disease
- Headache
- Dizziness or sleep disturbance
- Stroke warning signs requiring urgent care

Oral Formulation Related Effects

- Gastrointestinal discomfort
- Nausea or dyspepsia
- Hypersensitivity to raloxifene or excipients
- Tablet intolerance related to formulation ingredients
- Medication errors involving strength or frequency

The occurrence and severity of adverse effects vary with exposure, duration, underlying vascular risks, individual response, and concurrent medications.

CONTRAINDICATIONS

Condition	Reason
Active or Previous Venous Thromboembolism	Risk of recurrent venous clotting
Deep Vein Thrombosis History	Prior deep vein clot is a labeled exclusion
Pulmonary Embolism History	Prior pulmonary clot is a labeled exclusion
Retinal Vein Thrombosis History	Prior retinal venous clot is a labeled exclusion
Pregnancy	Potential fetal harm; no indicated benefit
Women Who May Become Pregnant	Not intended for premenopausal use
Breastfeeding	Potential infant exposure; contraindicated in labeling
Known Hypersensitivity	Risk of allergic reaction to raloxifene or excipients

DRUG INTERACTIONS

Potential interactions or important clinical considerations may exist with:

- Bile-acid sequestrants such as cholestyramine
- Warfarin and other anticoagulants
- Systemic estrogen therapies
- Highly protein-bound medicines
- Medicines affecting thrombotic risk
- Other osteoporosis therapies
- Hormonal therapies
- Drugs affecting hepatic or biliary function
- Laboratory tests influenced by hormonal status

Bile-acid sequestrants markedly reduce raloxifene absorption; anticoagulant monitoring may be needed when medicines are started or stopped. Other interactions require review of the exact treatment plan.

LABORATORY MONITORING

Laboratory Test	Purpose
Bone Mineral Density	Assess baseline and treatment-related skeletal health
Calcium / Vitamin D Status	Support bone-health management
Clinical VTE Review	Assess signs and risk factors for venous thrombosis
Stroke Risk Assessment	Review cardiovascular and cerebrovascular risk
Blood Pressure	Cardiovascular-risk monitoring
Lipid Profile	Assess underlying metabolic risk
ALT / AST	Evaluate liver function when clinically relevant
Pregnancy Testing	Exclude pregnancy when status is uncertain
Medication Interaction Review	Review anticoagulants, estrogen, and bile-acid sequestrants
Breast Health Assessment	Follow indicated screening and risk-reduction plan
Clinical Symptom Review	Monitor hot flashes, leg cramps, edema, and vascular symptoms

STORAGE AND STABILITY

- Store according to official product labeling.
- Protect from excessive heat, moisture, and direct sunlight.
- Keep the container tightly closed.
- Maintain original packaging integrity.
- Keep away from children.
- Inspect tablets and packaging before use.
- Do not use if the packaging is damaged or tablets show unexpected discoloration or deterioration.
- Storage requirements depend on the validated tablet formulation.

PRODUCT AUTHENTICITY

Every genuine NEXON product should include appropriate quality-verification features.

- Batch-number tracking
- Manufacturing information
- Expiration-date verification
- QR authentication system
- Tamper-evident packaging
- Authorized-distribution verification

NEXON emphasizes transparency, traceability, and product-quality control.

FREQUENTLY ASKED QUESTIONS

What is Raloxifene 60 mg?

It is a fictional oral tablet presentation containing 60 mg of raloxifene hydrochloride per tablet.

What class of medicine is raloxifene?

It is a selective estrogen receptor modulator with tissue-specific agonist and antagonist effects.

What does 60 mg represent?

It is the labeled amount of raloxifene hydrochloride contained in each tablet.

Is raloxifene an anabolic steroid?

No. It is a selective estrogen receptor modulator, not an anabolic-androgenic steroid.

Is raloxifene an aromatase inhibitor?

No. It modulates estrogen receptors rather than directly inhibiting estrogen synthesis.

Is it oral or injectable?

This product is presented as an oral tablet.

Does raloxifene treat breast cancer?

No. Approved use includes risk reduction in certain postmenopausal women, not treatment of established breast cancer.

Can raloxifene cause serious adverse effects?

Yes. It increases venous thromboembolism risk and may increase the risk of fatal stroke in susceptible women.

Does raloxifene require medical supervision?

Yes. Indication, menopausal status, vascular risk, contraindications, interactions, and monitoring need clinical review.

Is this specific NEXON 60 mg formulation FDA approved?

No. The displayed 60 mg tablet is a fictional catalog item and is not presented as an independently FDA-approved medicine.

NEXON QUALITY COMMITMENT

NEXON is committed to maintaining high standards of manufacturing quality, product consistency, traceability, and scientific transparency.

Through quality-control systems, authentication procedures, and responsible information sharing, NEXON aims to provide reliable pharmaceutical products and educational resources for healthcare professionals and informed users.

SCIENTIFIC REFERENCES

- U.S. Food and Drug Administration. EVISTA Raloxifene Hydrochloride Tablets Prescribing Information.
- DailyMed. Raloxifene Hydrochloride Tablets Official Drug Label.
- National Cancer Institute. Selective Estrogen Receptor Modulator Definition.
- National Cancer Institute. Breast Cancer Prevention Overview.
- Ettinger B, et al. Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis.
- Cummings SR, et al. Breast Cancer Risk Reduction with Raloxifene in Postmenopausal Women.
- Vogel VG, et al. Tamoxifen and Raloxifene for Breast Cancer Prevention in the STAR Trial.
- Barrett-Connor E, et al. Raloxifene and Cardiovascular Events in Postmenopausal Women.
- Delmas PD, et al. Raloxifene Effects on Bone Mineral Density and Bone Turnover.
- National Osteoporosis Foundation. Clinician Guidance on Osteoporosis Management.
- U.S. Preventive Services Task Force. Medication Use to Reduce Breast Cancer Risk.
- National Comprehensive Cancer Network. Breast Cancer Risk Reduction Guidelines.