

Raloxifene Hcl Cas No. : 82640-04-8

Raloxifene is used to prevent and treat bone loss (osteoporosis) in women after menopause. Maintaining strong bones by slowing bone loss helps to reduce the risk of fractures. This drug is different from hormones (including estrogens and progestins). It works by acting like estrogen (as a selective estrogen receptor modulator or SERM) in some parts of the body.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Raloxifene Hcl****CAS No. : 82640-04-8**Molecular Formula C₂₈H₂₇NO₄S.HCl;C₂₈H₂₈ClNO₄S

Molecular Weight 510.05

CAS Registry Number 82640-04-8

ATC code G03XC01

PubChem 5035

DrugBank APRD00400

Chemical dataFormula C₂₈H₂₇NO₄S

Mol. mass 473.584 g/mol

SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability 2%

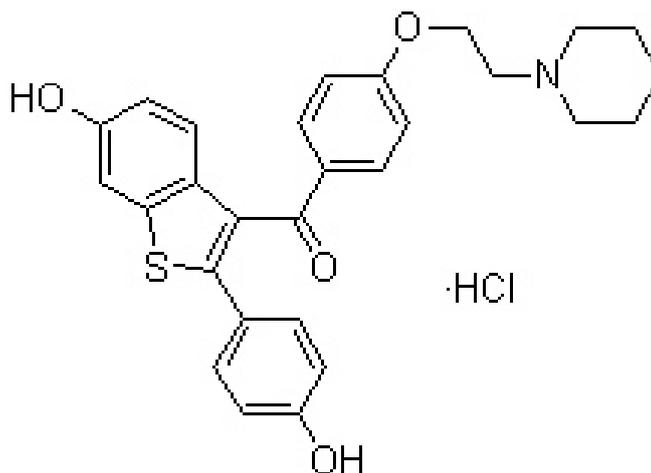
Protein binding 95%

Metabolism Hepatic glucuronidation

CYP system not involved

Half life 27.7 hours

Excretion Fecal

**DOSAGE**

There is only one standard dose of raloxifene hydrochloride regardless of your age, weight, or other medical conditions or medications. As is always the case, do not adjust your dose unless your healthcare provider specifically instructs you to do so. Raloxifene is approved to prevent and treat osteoporosis in postmenopausal women. It is also approved to lower the risk of breast cancer in postmenopausal women with osteoporosis, as well as postmenopausal women who are high risk for breast cancer. No matter what the use, the recommended dose is raloxifene 60 mg once daily. If you are taking raloxifene for osteoporosis treatment or prevention, it is important that you get enough calcium and vitamin D. Typically, most postmenopausal women need 1500 mg of calcium per day (divided into three smaller doses) and 400 to 800 international units (IU) of vitamin D per day. Some women (such as the elderly or chronically ill) may need even more vitamin D.

General Information on Dosing With Raloxifene

The medication comes in tablet form. It is usually taken by mouth once a day.

You can take raloxifene with or without food.

You can take raloxifene any time of the day, although it is best to take it at the same time each day.

For the medication to work properly, it must be taken as prescribed. Raloxifene will not work if you stop taking it.

If you are unsure about anything related to raloxifene or raloxifene dosing, talk with your doctor, nurse, or pharmacist.

Do not stop taking the drug without first discussing it with your healthcare provider.

SIDE EFFECTS

Side effects are possible with raloxifene hydrochloride however, not everyone who takes the drug will experience side effects. In fact, most people tolerate it quite well. If side effects do occur, in most cases, they are minor and either require no treatment or can easily be treated by you or your healthcare provider.



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Serious Side Effects of Raloxifene

Some side effects with raloxifene, while occurring infrequently, are potentially serious and should be reported immediately to your healthcare provider. These include, but are not limited to:

- * Signs of a blood clot in the leg, such as pain in the calf, leg cramps, and leg or foot swelling
- * Signs of a blood clot in the lung, such as shortness of breath, sharp chest pain, or coughing up blood
- * Signs of a stroke, such as vision or speech changes, weakness or numbness in an arm or leg, and a severe headache
- * Sudden loss of vision or vision changes, which can be a sign of a blood clot in the eye
- * High triglycerides
- * Depression (see Evista and Depression)
- * Gallstones or other gallbladder problems
- * Any unusual uterine bleeding
- * Signs of an allergic reaction, including unexplained rash, hives, itching, and unexplained swelling.

PRECAUTIONS

The medication can increase the risk of blood clots. You are at higher risk for blood clots if your mobility is limited due to surgery, bed rest, or traveling. In order to help prevent blood clots, raloxifene should be stopped at least three days before any surgery that will limit your mobility. While traveling, make sure that you try to move about periodically to keep the blood flowing through your legs. If you have a condition that may predispose you to blood clots (such as cancer or congestive heart failure), your healthcare provider should weigh the benefits of raloxifene against the risks of a blood clot. In one study of raloxifene in women with heart disease (or who were at high risk for heart problems), the medication increased the risk of death due to strokes. If you already have risk factors for a stroke (such as a prior stroke or mini-stroke, a heart arrhythmia, high blood pressure, or cigarette smoking), your healthcare provider should weigh the risk of a stroke against the benefits of raloxifene. Raloxifene should not be used to treat or prevent heart disease. Studies have shown that the drug is not effective for this use. Raloxifene has not been adequately studied in premenopausal women or in men. Also, the medication has not been adequately studied in women who have already had breast cancer.

Some women have a tendency to develop high triglycerides while taking an estrogen medication. Even though raloxifene is not an estrogen medication, it can act like estrogen in some ways. The drug may cause high triglycerides, especially in women who have a history of high triglycerides due to estrogen.

Let your healthcare provider know if you have liver or kidney disease, as your body may not handle raloxifene as well as it should.

Raloxifene can potentially interact with a number of medications

INTERACTION

Raloxifene hydrochloride can potentially interact with a number of other medications. Some of the medicines that may lead to drug interactions with raloxifene include:

Bile Acid Sequestrants

Bile acid sequestrant medications may bind to raloxifene in the digestive tract, preventing it from being absorbed into the body. This may make raloxifene less effective. Do not take raloxifene and a bile acid sequestrant at the same time. It is best to take these medications at least several hours apart.





Diazepam

Theoretically, raloxifene may interact with diazepam, since both medications are highly bound to proteins in the blood. However, since this interaction has not actually been studied, it is not known if taking these medications together will cause any problems. Your healthcare provider may choose to monitor you more closely in such a case.

Estrogen Medications

Raloxifene works like estrogen in some ways and like an anti-estrogen in other ways. As a result, it is possible that estrogen medications may make raloxifene less effective or may increase the risk of certain raloxifene side effects. Therefore, taking raloxifene with an estrogen is not recommended.

Thyroid Medications

There have been reports that raloxifene may make thyroid medications less effective, although this has not been confirmed in formal studies. Your healthcare provider may decide to monitor you more closely if you are taking both of these medications.

Warfarin

If you are taking both warfarin and raloxifene, your healthcare provider may need to monitor your prothrombin time ("pro time" -- a blood test to monitor people on warfarin) more closely, especially when you are starting or stopping raloxifene.

DRUG DESCRIPTION

Raloxifene HCl is an off-white to pale-yellow solid that is very slightly soluble in water.

Raloxifene HCl is supplied in a tablet dosage form for oral administration. Each Raloxifene HCl tablet contains 60 mg of raloxifene HCl, which is the molar equivalent of 55.71 mg of free base. Inactive ingredients include anhydrous lactose, carnauba wax, crospovidone, FD&C Blue No. 2 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, modified pharmaceutical glaze, polyethylene glycol, polysorbate 80, povidone, propylene glycol, and titanium dioxide.

EVISTA is the only medicine proven to reduce both the risk of spinal fractures due to osteoporosis and the risk of invasive breast cancer in postmenopausal women with osteoporosis. EVISTA does not treat breast cancer, prevent it from returning, or reduce the risk of all forms of breast cancer. Raloxifene is prescribed to treat postmenopausal women for osteoporosis. Raloxifene uses are primarily concerned with both osteoporosis and breast cancer. This page of the eMedTV Web site explains why raloxifene is used for both conditions, how it works in the body, and also addresses off-label uses and uses in children.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

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91 022 30601000.

This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).

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