

Package leaflet: Information for the user

Evista 60 mg film-coated tablets
raloxifene hydrochloride

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience a lot of discomfort from one of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist. See section 4.

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1. What is this medicine used for?

Evista contains the active substance raloxifene hydrochloride.

Evista is used for the treatment of osteoporosis in postmenopausal women and for the prevention of osteoporosis. Evista reduces the risk of vertebral fractures in postmenopausal women with osteoporosis. It has not been shown to reduce the risk of hip fractures.

How does this medicine work?

Evista belongs to a group of non-hormonal medicines called selective estrogen receptor modulators (SERMs). When a woman reaches menopause, the amount of the female sex hormone estrogen decreases. Evista mimics some of the beneficial effects of estrogen after menopause.

Osteoporosis is a disease that makes your bones thin and fragile - this condition occurs especially in women after menopause. Although there may be no symptoms initially, osteoporosis increases the risk of bone fractures, particularly in your spine, hips, and wrists, and can cause back pain, loss of height, and a curved back.

2. When should you not take this medicine or be extra careful with it?

When should you not take this medicine?

- You are being treated or have been treated for blood clots in the legs (deep vein thrombosis), in the lungs (pulmonary embolism), or in the eyes (retinal vein thrombosis).
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You can still become pregnant, in which case Evista can harm your unborn child.
- You have a liver disease (for example, liver cirrhosis, mild liver impairment or jaundice).
- You have severe kidney problems.
- You have unexplained vaginal bleeding. This should be investigated by your doctor (see next paragraph).
- You have uterine cancer. There is insufficient experience in the use of Evista in women with this disease.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine:

- If you are immobile for some time, such as being wheelchair-bound, requiring hospitalization, or needing to stay in bed while recovering from surgery, or an unexpected illness, as this increases your risk of developing blood clots (deep vein thrombosis, pulmonary embolism, or thrombosis in the retinal vein).
- If you have had a stroke (e.g., cerebrovascular accident), or if your doctor has told you that you are at high risk of having one.
- If you have liver disease.
- If you have breast cancer, because there is insufficient experience with the use of Evista in women with this disease.
- If you are receiving oral estrogen therapy.

It is unlikely that Evista can cause vaginal bleeding. Any vaginal bleeding during treatment with Evista is therefore unexpected. You should have this examined by your doctor.

Evista does not affect postmenopausal symptoms such as hot flashes.

Evista lowers total cholesterol and LDL ("bad") cholesterol. It generally does not change triglycerides or HDL ("good") cholesterol. However, if you have previously used estrogens and have had extreme increases in triglycerides, you should discuss this with your doctor before you start using Evista.

Evista contains lactose

If your doctor has told you that you cannot tolerate lactose, a certain type of sugar, contact your doctor before taking this medicine.

Are you taking any other medicines?

Are you taking any other medicines besides Evista, or have you recently taken any, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist.

If you are using digitalis medicines for your heart or anticoagulants such as warfarin to thin your blood, your doctor may need to adjust your dosage for these medicines.

Tell your doctor when you are using cholestyramine, which is mainly used as a lipid-lowering medicine, because there is a chance that Evista may work less effectively.

Pregnancy and breastfeeding

Evista is only for use by postmenopausal women and should not be taken by women who could still have a baby. Evista could harm your unborn child.

Evista should not be used during the period of breastfeeding, as it may be excreted in breast milk.

Driving and using machines

Evista has no or negligible influence on the ability to drive and use machines.

3. How do you take this medicine?

Always take this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The dosage is 1 tablet per day. It does not matter what time of day you take your tablet, but taking it at the same time every day helps you not to forget the tablet. You can take it with or without food.

The tablets are for oral use.

Swallow the tablet whole. If you wish, you can drink a glass of water with it. Do not break or crush the tablet before taking it. A broken or crushed tablet may taste bad and there is a chance you may take an incorrect dose.

Your doctor will tell you how long you need to continue using Evista. The doctor may also advise using calcium supplementation and vitamin D supplementation.

Have you taken too much of this medicine?

Then tell your doctor or pharmacist. If you have taken too much of this medicine, you may develop leg cramps and dizziness.

Have you forgotten to take this medicine?

Take a tablet as soon as you remember and take the next tablets as you normally would. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

First contact your doctor.

It is important that you continue taking Evista as long as your doctor has prescribed it for you. Evista can only treat or prevent your osteoporosis if you continue taking the tablets.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. The majority of side effects seen with Evista have been mild.

The most common side effects (occurring in more than 1 in 10 users) are:

- Hot flushes (vasodilation)
- Flu-like symptoms
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain, and stomach discomfort
- Increased blood pressure

Common side effects (occurring in 1 to 10 out of 100 users) are:

- Headache, including migraine
- Leg cramps
- Swollen hands, feet, and legs (peripheral edema)
- Gallstones.
- Rash
- Mild breast symptoms such as breast pain, enlarged breasts, and tender breasts.

Uncommon side effects (occurring in 1 to 10 out of 1000 users) are:

- Increased risk of blood clots in the legs (deep vein thrombosis)
- Increased risk of blood clots in the lungs (pulmonary embolism)
- Increased risk of blood clots in the eyes (retinal vein thrombosis)
- Red and painful skin around the vein (superficial vein inflammation)
- Blood clot in an artery; this can, for example, lead to a stroke, including an increased risk of dying from a stroke
- Decrease in the number of platelets

In rare cases, blood levels of liver enzymes may be increased during treatment with Evista.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist.

This also applies to possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store in the original package. Do not freeze.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is raloxifene hydrochloride. Each tablet contains 60 mg of raloxifene hydrochloride, equivalent to 56 mg of raloxifene.
- The other substances in this medicine are:
Tablet core: Povidone, polysorbate 80, anhydrous lactose, lactose monohydrate, crospovidone, magnesium stearate.
Tablet coating: Titanium dioxide (E171), hypromellose, macrogol 400.

What does Evista look like and how much is in a package?

Evista tablets are white, oval, film-coated tablets. They are packed in strips or in plastic bottles. The strip packs contain 14, 28, or 84 tablets. The bottles contain 100 tablets. It is possible that not all pack sizes are marketed in every country.

Marketing authorization holder

SUBSTIPHARM, 24 rue Erlanger, 75016 Paris, France.

Manufacturer

- INPHARMASCI, ZI N°2 de Prouvy-Rouvignies, 1 rue de Nungesser, 59121 Prouvy, France.

For all information regarding this medicine, contact the local representative of the marketing authorization holder:

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This leaflet was last approved in month YYYY

More information about this medicine is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).