

Patient Information

EVISTA[®] (E-VISS-tah) (raloxifene hydrochloride) Tablets

Read the patient information before you start taking EVISTA. Also, read the leaflet each time you refill your prescription, just in case anything has changed. This leaflet does not take the place of talking with your doctor about your medical condition or treatment. Talk with your doctor about EVISTA when you start taking it and at regular checkups.

What is the most important information I should know about EVISTA?

- If you have leg pain, swelling of the legs, hands or feet, sudden chest pain, shortness of breath, coughing up blood, a sudden change in your vision (such as loss of vision or blurred vision) or have had blood clots in your leg, lung or eye, stop taking EVISTA and call your doctor. (See “Who should not take EVISTA” and “What are the possible side effects of EVISTA?”)
- Being still for a long time (such as sitting still during a long car or airplane trip or being in bed after surgery) can increase your risk of blood clots. (See “What should I avoid if I am taking EVISTA?”)
- If you have or have had a stroke, mini-stroke (TIA/transient ischemic attack), or a type of irregular heartbeat (atrial fibrillation), talk with your doctor about whether it is all right to take EVISTA. (See “What are the possible side effects of EVISTA?”)

What is EVISTA?

EVISTA is a prescription medicine for women after menopause to treat or prevent osteoporosis. You should take calcium and vitamin D along with EVISTA if you do not get enough calcium and vitamin D in your diet.

EVISTA **treats** osteoporosis by helping make bones stronger and less likely to break. It helps **prevent** osteoporosis by building bone and stopping the thinning of bone that occurs after menopause. When a woman goes through menopause, her body produces less estrogen. One result of having less estrogen is that the bones of some women get thinner and weaker. This thinning of the bone is called osteoporosis. Osteoporosis can lead to broken bones (fractures).

EVISTA is not for use in premenopausal women.

Who should not take EVISTA?

Do not take EVISTA if you:

- are pregnant or could become pregnant. EVISTA could harm your unborn child.
- are nursing a baby. It is not known if EVISTA passes into breast milk or what effect it might have on the baby.

- have or have had blood clots that required a doctor's treatment. This may include clots in the legs, lungs, or eyes. Taking EVISTA may increase the risk of getting these blood clots. While infrequent, these clots can cause serious medical problems, disability, or death. If anyone in your family has a history of blood clots, or if you are now being treated for congestive heart failure or cancer, talk with your doctor about whether it is all right to take EVISTA.

What should I tell my doctor before taking EVISTA?

EVISTA may not be right for you. Before taking EVISTA, tell your doctor about all your medical conditions, including if you:

- have had blood clots in your legs, lungs, or eyes, a stroke, mini-stroke (TIA/transient ischemic attack), or a type of irregular heartbeat (atrial fibrillation).
- have had breast cancer. EVISTA has not been fully studied in women who have a history of breast cancer.
- have liver or kidney problems.
- have taken estrogen in the past and had extreme elevations in triglycerides.
- are pregnant, planning to become pregnant, or breast-feeding.

Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take EVISTA?

Keep taking EVISTA for as long as your doctor prescribes it for you. EVISTA can treat or prevent osteoporosis only if you take it regularly. This is why it is important to get your refills on time so you do not run out of the medicine.

- Take one EVISTA tablet each day.
- EVISTA can be taken at any time of the day with or without food.
- To help you remember to take EVISTA, it may be best to take it at about the same time each day.
- Calcium and/or vitamin D may be taken at the same time as EVISTA.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose. Do not take two doses at the same time.

What should I avoid while taking EVISTA?

Being still for a long time (such as during prolonged travel or being in bed after surgery) can increase the risk of blood clots. EVISTA may add to this risk. If you will need to be still for a long time, you should talk with your doctor about ways to reduce the risk of blood clots. On long trips, you should move around periodically. You should stop taking EVISTA at least 3 days before a planned surgery or before you plan on being still for a long time. You should start

taking EVISTA again when you return to your normal activities. (See “**What are the possible side effects of EVISTA?**”)

Some medicines that should not be taken with EVISTA are:

- any form of estrogen therapy that comes as a pill, patch or injection
- cholestyramine or colestipol

If you are taking warfarin or other coumarin blood thinners, your doctor may need to do a blood test when you first start or if you need to stop taking EVISTA. Names for this test include “prothrombin time,” “pro-time,” or “INR.” Your doctor may need to adjust the dose of your warfarin or other coumarin blood thinner.

What are the possible side effects of EVISTA?

Infrequent but serious side effects of taking EVISTA include the development of blood clots in the veins **and death due to stroke.** Blood clots in the veins can stop blood flow and cause serious medical problems, disability or death.

Stop taking EVISTA and call your doctor right away if you have any of these signs of **possible** blood clots in the legs, lungs or eyes:

- leg pain or a feeling of warmth in the lower leg (calf)
- swelling of the legs, hands or feet
- sudden chest pain, shortness of breath or coughing up blood
- sudden change in your vision, such as loss of vision or blurred vision

If you have or have had a stroke, mini-stroke (TIA/transient ischemic attack), or a type of irregular heartbeat (atrial fibrillation), talk with your doctor about whether it is all right to take EVISTA.

The most common side effects of EVISTA are hot flashes and leg cramps. Hot flashes are more common during the first 6 months after starting treatment.

These are not all the side effects of EVISTA. Tell your doctor about any side effect that bothers you or that does not go away. If you have any problems or questions that concern you while taking EVISTA, ask your doctor or pharmacist for more information.

What else should I know about EVISTA?

Do not use EVISTA to prevent heart disease, heart attack or strokes.

To get the calcium and vitamin D you need, your doctor may advise you to change your diet and/or take supplemental calcium and vitamin D. Your doctor may suggest other ways to help treat or prevent osteoporosis, in addition to taking EVISTA and getting the calcium and vitamin D you need. These may include **regular** exercise, stopping smoking and drinking less alcohol.

Women who have hot flashes can take EVISTA. However, EVISTA does not treat hot flashes, and it may cause hot flashes in some women. (See “What are the possible side effects of EVISTA?”)

EVISTA has not been found to cause breast tenderness or enlargement. If you notice any changes in your breasts, you should contact your doctor to find out the cause. **In clinical studies, EVISTA did not increase the risk for breast cancer.**

EVISTA should not cause spotting or menstrual-type bleeding. If you have any vaginal bleeding, you should contact your doctor to find out the cause. EVISTA has not been found to increase the risk for cancer of the lining of the uterus.

How should I store EVISTA?

- Store EVISTA at 68°F to 77°F (20°C -25°C).
- Keep EVISTA and all medicines out of the reach of children.

General Information about the safe and effective use of EVISTA

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use EVISTA for a condition for which it was not prescribed. Do not give your EVISTA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet is a summary of the most important information about EVISTA. If you would like more information about EVISTA talk with your doctor. You can ask your doctor or pharmacist for information about EVISTA that is written for health professionals. For more information, call 1-800-545-5979 (toll-free) or go to the following website: www.evista.com.

What are the ingredients in EVISTA?

Active ingredient: raloxifene hydrochloride

Inactive Ingredients: 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.

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