

INFORMATION FOR THE PATIENT

EVISTA[®] (Ē-VISS-tah) Tablets

Generic name: raloxifene hydrochloride

Important Information for Patients Using EVISTA for the Treatment and Prevention of Osteoporosis after Menopause

Read this information carefully before you start taking EVISTA tablets. It is also important to read this information each time you get your refill in case new information is available. This summary does not tell you everything about EVISTA. Talk with your doctor or pharmacist if there is something you do not understand or if you want to learn more about EVISTA. Be sure to talk with your doctor before you start taking EVISTA and during your regular checkups. Your doctor is your best source of information about this medicine. Always follow your doctor's instructions on how to take EVISTA.

What is EVISTA?

EVISTA is a prescription medicine used by women after menopause to treat or prevent a condition called 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). This is why women should learn what they can do to treat or prevent osteoporosis.

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 getting certain types of exercise, quitting smoking and drinking less alcohol.

Who should not take EVISTA?

Do not take EVISTA if:

- your doctor has **not** told you that you have passed menopause. EVISTA is for use only by women **after menopause**.
- **you are pregnant or could become pregnant. EVISTA could harm your unborn child.**
- **you are nursing a baby. It is not known if EVISTA passes into breast milk or what effect it might have on the baby.**
- you 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.

- you have severe liver disease, unless your doctor says it is all right to take EVISTA.
- you are allergic to EVISTA or any of its ingredients. The active ingredient in EVISTA is raloxifene hydrochloride. See **“What else should I know about EVISTA?”** for a list of the inactive ingredients.

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 if I am taking EVISTA?

Immobility

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 Other Medicines

Always tell your doctor and pharmacist about all the medicines you are taking or start taking, including EVISTA. These include all prescription medicines as well as over-the-counter (non-prescription) and herbal medicines. Your doctor and pharmacist need this information to help prevent drug interactions that might harm you.

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?

An infrequent but serious side effect of taking EVISTA is the development of blood clots in the veins. These blood clots can stop blood flow and cause serious medical problems, disability or death. Call your doctor right away if you have or have had any of the following signs of blood clots in the legs, lungs or eyes:

- leg pain or a feeling of warmth in the calves
- 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

Most of the side effects of EVISTA are mild and usually do not cause women to stop taking 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.

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?

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.

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.

In clinical studies, EVISTA did not increase the risk for breast cancer.

EVISTA lowers total cholesterol by about 7% and LDL (“bad”) cholesterol by about 11%, on average. In general, it does not change triglycerides or HDL (“good”) cholesterol. However, if you have taken estrogen in the past and had extreme elevations in triglycerides, you should talk with your doctor before taking EVISTA.

Call your doctor if you become pregnant while taking EVISTA.

Keep EVISTA and all medicines away from children. In case of overdose, call your doctor, hospital or poison control center right away.

Medicines are sometimes prescribed for purposes not listed in this patient information. EVISTA has been prescribed just for you. Do not share your medicine with anyone else even if she has a similar condition. Her doctor should decide if EVISTA is right for her.

If you have any questions, ask your doctor. If you want to read more about EVISTA, ask your doctor or pharmacist to give you the information on EVISTA written for health professionals. The EVISTA web site (www.evista.com) also has this detailed information.

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. EVISTA does not contain enough lactose to cause symptoms in women who have lactose intolerance.

Literature revised July 11, 2003

Eli Lilly and Company, Indianapolis, IN 46285, USA

PV 3122 AMP

PRINTED IN USA

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