the fetus if this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug.

EVISTA is contraindicated in women with active or past history of venous thromboembolic events, including deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis.

EVISTA is contraindicated in women known to be hypersensitive to raloxifene or other constituents of the tablets.

WARNINGS

Venous Thromboembolism–In clinical trials, EVISTA-treated women had an increased risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism). Other venous thromboembolic events could also occur. A less serious event, superficial thrombophlebitis, also has been reported more frequently with EVISTA. The greatest risk for deep vein thrombosis and pulmonary embolism occurs during the first 4 months of treatment, and the magnitude of risk appears to be similar to the reported risk associated with use of hormone replacement therapy. Because immobilization increases the risk for venous thromboembolic events independent of therapy, EVISTA should be discontinued at least 72 hours prior to and during prolonged immobilization (e.g., post-surgical recovery, prolonged bed rest), and EVISTA therapy should be resumed only after the patient is fully ambulatory. In addition, women taking EVISTA should be advised to move about periodically during prolonged travel. The risk-benefit balance should be considered in women at risk of thromboembolic disease for other reasons, such as congestive heart failure, superficial thrombophlebitis and active malignancy.

Premenopausal Use–There is no indication for premenopausal use of EVISTA. Safety of EVISTA in premenopausal women has not been established and its use is not recommended (see CONTRAINDICATIONS).

Hepatic Dysfunction–Raloxifene was studied, as a single dose, in Child-Pugh Class A patients with cirrhosis and serum total bilirubin ranging from 0.6 to 2.0 mg/dL. Plasma raloxifene concentrations were approximately 2.5 times higher than in controls and correlated with total bilirubin concentrations. Safety and efficacy have not been evaluated further in patients with severe hepatic insufficiency.

PRECAUTIONS

General

Concurrent Estrogen Therapy–The concurrent use of EVISTA and systemic estrogen or hormone replacement therapy (ERT or HRT) has not been studied in prospective clinical trials and therefore concomitant use of EVISTA with systemic estrogens is not recommended.

Lipid Metabolism–EVISTA lowers serum total and LDL cholesterol by 6% to 11%, but does not affect serum concentrations of total HDL cholesterol or triglycerides.

These effects should be taken into account in therapeutic decisions for patients who may require therapy for hyperlipidemia.

Concurrent use of EVISTA and lipid-lowering agents has not been studied.

Endometrium--EVISTA has not been associated with endometrial proliferation (see **Clinical Studies** and ADVERSE REACTIONS). Unexplained uterine bleeding should be investigated as clinically indicated.

Breast--EVISTA has not been associated with breast enlargement, breast pain, or an increased risk of breast cancer (see **Clinical Studies** and ADVERSE REACTIONS). Any unexplained breast abnormality occurring during EVISTA therapy should be investigated.

History of Breast Cancer--EVISTA has not been adequately studied in women with a prior history of breast cancer.

Use in Men--Safety and efficacy have not been evaluated in men.

Information for Patients

For safe and effective use of EVISTA, the physician should inform patients about the following:

Patient Immobilization--EVISTA should be discontinued at least 72 hours prior to and during prolonged immobilization (e.g., post-surgical recovery, prolonged bed rest), and patients should be advised to avoid prolonged restrictions of movement during travel because of the increased risk of venous thromboembolic events.

Hot Flashes or Flushes--EVISTA may increase the incidence of hot flashes and is not effective in reducing hot flashes or flushes associated with estrogen deficiency. In some asymptomatic patients, hot flashes may occur upon beginning EVISTA therapy.

Other Osteoporosis Treatment and Prevention Measures--Patients should be instructed to take supplemental calcium and/or vitamin D, if daily dietary intake is inadequate. Weight-bearing exercise should be considered along with the modification of certain behavioral factors, such as cigarette smoking, and/or alcohol consumption, if these factors exist.

Physicians should instruct their patients to read the patient package insert before starting therapy with EVISTA and to re-read it each time the prescription is renewed.

Drug Interactions

Cholestyramine--Cholestyramine, an anion exchange resin, causes a 60% reduction in the absorption and enterohepatic cycling of raloxifene after a single dose. Co-administration of cholestyramine with EVISTA is not recommended. Although not specifically studied, it is anticipated that other anion exchange resins would have a similar effect.

Warfarin--In vitro, raloxifene did not interact with the binding of warfarin. The co-administration of EVISTA and warfarin, a coumarin derivative, has been assessed in a single dose study. In this study, raloxifene had no effect on the pharmacokinetics of warfarin. However, a 10% decrease in prothrombin time was observed in the single-dose study. If EVISTA is given concurrently with warfarin or other coumarin derivatives, prothrombin time should be monitored more closely when starting or stopping therapy with EVISTA. In the osteoporosis treatment trial, there were no clinically relevant effects of warfarin co-administration on plasma concentrations of raloxifene.

Other Highly Protein-Bound Drugs--Raloxifene is more than 95% bound to plasma proteins. Other highly protein-bound drugs should not cause clinically relevant changes in EVISTA plasma concentrations. Furthermore, in the osteoporosis treatment trial, there were no clinically relevant effects of co-administration of other highly protein-bound drugs (e.g., gemfibrozil) on plasma concentrations of raloxifene. In vitro, raloxifene did not interact with the binding of phenytoin, tamoxifen, or warfarin (see above). Although not

examined, EVISTA might affect the protein binding of other drugs and should be used with caution with certain other highly protein-bound drugs such as diazepam, diazoxide and lidocaine.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenesis:

In a 21-month carcinogenicity study in mice, there was an increased incidence of ovarian tumors in female animals given 9 to 242 mg/kg, which included benign and malignant tumors of granulosa/theca cell origin and benign tumors of epithelial cell origin. Systemic exposure (AUC) of raloxifene in this group was 0.3 to 34 times that in postmenopausal women administered a 60-mg dose. There was also an increased incidence of testicular interstitial cell tumors and prostatic adenomas and adenocarcinomas in male mice given 41 or 210 mg/kg (4.7 or 24 times the AUC in humans), and prostatic leiomyoblastoma in male mice given 210 mg/kg.

In a 2-year carcinogenicity study in rats, an increased incidence in ovarian tumors of granulosa/theca cell origin was observed in female rats given 279 mg/kg (approximately 400 times the AUC in humans). The female rodents in these studies were treated during their reproductive lives when their ovaries were functional and responsive to hormonal stimulation.

Mutagenesis:

Raloxifene HCl was not genotoxic in any of the following test systems: the Ames test for bacterial mutagenesis with and without metabolic activation, the unscheduled DNA synthesis assay in rat hepatocytes, the mouse lymphoma assay for mammalian cell mutation, the chromosomal aberration assay in Chinese hamster ovary cells, the in vivo sister chromatid exchange assay in Chinese hamsters, and the in vivo micronucleus test in mice.

Impairment of Fertility:

When male and female rats were given daily doses ≥5 mg/kg (≥0.8 times the human dose based on surface area, mg/m^2) prior to and during mating, no pregnancies occurred. In male rats, daily doses up to 100 mg/kg (16 times the human dose based on surface area, mg/m^2) for at least 2 weeks did not affect sperm production or quality, or reproductive performance. In female rats, at doses of 0.1 to 10 mg/kg/day (0.02 to 1.6 times the human dose based on surface area, mg/m^2), raloxifene disrupted estrous cycles and inhibited ovulation. These effects of raloxifene were reversible. In another study in rats in which raloxifene was given during the preimplantation period at doses ≥0.1 mg/kg (≥0.02 times the human dose based on surface area, mg/m^2), raloxifene delayed and disrupted embryo implantation resulting in prolonged gestation and reduced litter size. The reproductive and developmental effects observed in animals are consistent with the estrogen receptor activity of raloxifene.

Pregnancy

Pregnancy Category X--EVISTA should not be used in women who are or may become pregnant (see CONTRAINDICATIONS).

Nursing Mothers--EVISTA should not be used by lactating women (see CONTRAINDICATIONS). It is not known whether raloxifene is excreted in human milk.

Pediatric Use--EVISTA should not be used in pediatric patients.

Geriatric Use--In the osteoporosis treatment trial of 7705 postmenopausal women, 4621 women were considered geriatric (greater than 65 years old). Of these, 845 women were greater than 75 years old. Safety and efficacy in older and younger postmenopausal women in the osteoporosis treatment trial appeared to be comparable.

ADVERSE REACTIONS

Adverse Events in the Osteoporosis Treatment Clinical Trial

The safety of raloxifene in the treatment of osteoporosis was assessed in a large (7705 patients) multinational placebo-controlled trial. Duration of treatment was 36 months and 5129 postmenopausal women were exposed to raloxifene (2557 received 60 mg/day and 2572 received 120 mg/day).

The majority of adverse events occurring during the study were mild and generally did not require discontinuation of therapy.

Therapy was discontinued due to an adverse event in 10.9% of EVISTA-treated women and 8.8% of placebo-treated women. Common adverse events considered to be related to EVISTA therapy were hot flashes and leg cramps. Hot flashes were most commonly reported during the first 6 months of treatment and were not different from placebo thereafter.

Adverse Events in Placebo-Controlled Clinical Trials to Support the Osteoporosis Prevention Indication

The safety of raloxifene has been assessed primarily in 12 Phase 2 and Phase 3 studies with placebo, estrogen, and estrogen-progestin replacement therapy (HRT) control groups. The duration of treatment ranged from 2 to 30 months and 2036 women were exposed to raloxifene (371 patients received 10 to 50 mg/day, 828 received 60 mg/day, and 837 received from 120 to 600 mg/day).

The majority of adverse events occurring during clinical trials were mild and generally did not require discontinuation of therapy.

Therapy was discontinued due to an adverse event in 11.4% of 581 EVISTA-treated women and 12.2% of 584 placebo-treated women. Common adverse events considered to be drug-related were hot flashes and leg cramps (see Table 6). The first occurrence of hot flashes was most commonly reported during the first 6 months of treatment. Discontinuation rates due to hot flashes did not differ significantly between EVISTA and placebo groups (1.7% and 2.2%, respectively).

Table 6 lists adverse events occurring in either the osteoporosis treatment or the prevention placebo-controlled clinical trial databases at a frequency ≥2.0% in either group and in more EVISTA-treated women than in placebo-treated women. Adverse events are shown without attribution of causality.

Table 6. Adverse events occurring in placebo-controlled osteoporosis clinical trials at a frequency ≥2.0% and in more EVISTA-treated (60 mg once daily) women than placebo-treated women

	Treatment		Prevention	
	EVISTA N=2557	Placebo N=2576	EVISTA N=581	Placebo N=584
Body System	%	%	%	%
Body as a Whole				
Infection	A	A	15.1	14.6
Flu Syndrome	13.5	11.4	14.6	13.5
Headache	9.2	8.5	A	A
Leg Cramps	7.0	3.7	5.9	1.9
Chest Pain	A	A	4.0	3.6
Fever	3.9	3.8	3.1	2.6
Cardiovascular System				
Hot Flashes	9.7	6.4	24.6	18.3
Migraine	A	A	2.4	2.1
Syncope	2.3	2.1	B	B
Varicose Vein	2.2	1.5	A	A
Digestive System				
Nausea	8.3	7.8	8.8	8.6
Diarrhea	7.2	6.9	A	A
Dyspepsia	A	A	5.9	5.8
Vomiting	4.8	4.3	3.4	3.3
Flatulence	A	A	3.1	2.4
Gastrointestinal Disorder	A	A	3.3	2.1
Gastroenteritis	B	B	2.6	2.1
Metabolic and Nutritional				
Weight Gain	A	A	8.8	6.8
Peripheral Edema	5.2	4.4	3.3	1.9
Musculoskeletal System				
Arthralgia	15.5	14.0	10.7	10.1
Myalgia	A	A	7.7	6.2
Arthritis	A	A	4.0	3.6
Tendon Disorder	3.6	3.1	A	A
Nervous System				
Depression	A	A	6.4	6.0
Insomnia	A	A	5.5	4.3
Vertigo	4.1	3.7	A	A
Neuralgia	2.4	1.9	B	B
Hypesthesia	2.1	2.0	B	B
Respiratory System				
Sinusitis	7.9	7.5	10.3	6.5
Rhinitis	10.2	10.1	A	A

Bronchitis	9.5	8.6	A	A
Pharyngitis	5.3	5.1	7.6	7.2
Cough Increased	9.3	9.2	6.0	5.7
Pneumonia	A	A	2.6	1.5
Laryngitis	B	B	2.2	1.4
Skin and Appendages				
Rash	A	A	5.5	3.8
Sweating	2.5	2.0	3.1	1.7
Special Senses				
Conjunctivitis	2.2	1.7	A	A
Urogenital System				
Vaginitis	A	A	4.3	3.6
Urinary Tract Infection	A	A	4.0	3.9
Cystitis	4.6	4.5	3.3	3.1
Leukorrhea	A	A	3.3	1.7
Uterine Disorder[a,b]	3.3	2.3	A	A
Endometrial Disorder[a]	B	B	3.1	1.9
Vaginal Hemorrhage	2.5	2.4	A	A
Urinary Tract Disorder	2.5	2.1	A	A

A Placebo incidence greater than or equal to EVISTA incidence.

B Less than 2% incidence and more frequent with EVISTA.

a Treatment-emergent uterine-related adverse event, including only patients with an intact uterus: Prevention Trials: EVISTA, n=354, Placebo, n=364; Treatment Trial: EVISTA, n=1948, Placebo, n=1999.

b Actual terms most frequently referred to endometrial fluid.

Comparison of EVISTA and Hormone Replacement Therapy Adverse Events

EVISTA was compared with estrogen-progestin replacement therapy (HRT) in 3 clinical trials for prevention of osteoporosis. Table 7 shows adverse events occurring more frequently in one treatment group and at an incidence ≥2.0% in any group. Adverse events are shown without attribution of causality.

Table 7. Adverse events reported in the clinical trials for osteoporosis prevention with EVISTA (60 mg once daily) and continuous combined or cyclic estrogen plus progestin (HRT) at an incidence ≥2.0% in any treatment group[a]

Adverse Event	EVISTA (N=317) %	HRT-Continuous Combined (N=96) %	HRT-Cyclic (N=219) %
Urogenital			
Breast Pain	4.4	37.5	29.7
Vaginal Bleeding[b]	6.2	64.2	88.5
Digestive			
Flatulence	1.6	12.5	6.4
Cardiovascular			
Hot Flashes	28.7	3.1	5.9
Body as a Whole			
Infection	11.0	0	6.8
Abdominal Pain	6.6	10.4	18.7
Chest Pain	2.8	0	0.5

a These data are from both blinded and open-label studies.

b Treatment-emergent uterine-related adverse event, including only patients with an intact uterus: EVISTA, n=290, HRT-Continuous Combined, n=67, HRT-Cyclic, n=217.

Continuous Combined HRT = 0.625 mg conjugated estrogens plus 2.5 mg medroxyprogesterone acetate.

Cyclic HRT = 0.625 mg conjugated estrogens for 28 days with concomitant 5 mg medroxyprogesterone acetate or 0.15 mg norgestrel on days 1 through 14 or 17 through 28.

Laboratory Changes

The following changes in analyte concentrations are commonly observed during EVISTA therapy: increased apolipoprotein A1; and reduced serum total cholesterol, LDL cholesterol, fibrinogen, apolipoprotein B, and lipoprotein (a). EVISTA modestly increases hormone-binding globulin concentrations, including sex steroid-binding globulin, thyroxine-binding globulin, and corticosteroid-binding globulin with corresponding increases in measured total hormone concentrations. There is no evidence that these changes in hormone-binding globulin concentrations affect concentrations of the corresponding free hormones.

There were small decreases in serum total calcium, inorganic phosphate, total protein, and albumin which were generally of lesser magnitude than decreases observed during ERT/HRT. Platelet count was also decreased slightly and was not different from ERT.

Additional Safety Information

In the osteoporosis treatment trial of 36 months duration, EVISTA was not associated with deterioration of cognitive function or a change in affect, based on prospective, objective testing.

Incidences of estrogen-dependent carcinoma of the endometrium and breast are being evaluated across all completed and ongoing clinical trials involving 17,151 patients, of which at least 10,850 women have received at least one dose of raloxifene. These trials provided over 21,000 person-years of raloxifene exposure with a maximum exposure of 58 months.

Endometrium--Compared to placebo, raloxifene did not increase the risk of endometrial cancer.

Breast--Compared to placebo, raloxifene did not increase the risk of breast cancer (see CLINICAL PHARMACOLOGY, **Effects on the Breast**).

OVERDOSAGE

Incidents of overdose in humans have not been reported. In an 8-week study of 63 postmenopausal women, a dose of raloxifene HCl 600 mg/day was safely tolerated. No mortality was seen after a single oral dose in rats or mice at 5000 mg/kg (810 times the human dose for rats and 405 times the human dose for mice based on surface area, mg/m^2) or in monkeys at 1000 mg/kg (80 times the AUC in humans). There is no specific antidote for raloxifene.

DOSAGE AND ADMINISTRATION

The recommended dosage is one 60-mg EVISTA tablet daily which may be administered any time of day without regard to meals.

HOW SUPPLIED

EVISTA 60-mg tablets are white, elliptical, and film coated. They are imprinted on one side with LILLY and the tablet code 4165 in edible blue ink. They are available as follows:

Bottle (count)	NDC Number
30 (unit of use)	NDC - 0002-4165-30
100 (unit of use)	NDC - 0002-4165-02
2000	NDC - 0002-4165-07

Store at controlled room temperature, 20° to 25°C (68° to 77°F) [see USP]. The USP defines controlled room temperature as a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

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Eli Lilly and Company, Indianapolis, IN 46285, USA

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INFORMATION FOR THE PATIENT

EVISTA® (E-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. It does not change triglycerides or HDL ("good") cholesterol.

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, hydroxypropyl methylcellulose, 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.

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