Patient package insert in accordance with the pharmacists' regulations (preparations) – 1986

The dispensing of this medicine requires a doctor's prescription

EVISTA

Coated tablets

Active ingredients: Each coated tablet contains Raloxifene HCl 60 mg.
Inactive ingredients and allergens: See chapter 6 *"Additional information"*.

Please read this package insert carefully in its entirety before using this medicine. This package insert contains concise information on the medicine. If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not give it to other patients. It may harm them even if their condition seems similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Evista is used for the treatment and prevention of osteoporosis in postmenopausal women. **Evista** is used for the prevention of osteoporosis in postmenopausal women when estrogen therapy is considered unsuitable.

Prevention of breast cancer - **Evista** reduces the risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk for invasive breast cancer.

Therapeutic group:
Evista belongs to the non-hormonal drug group known as Selective Estrogen Receptor Modulators (SERMs). When a woman reaches menopause, the level of the sex hormone estrogen decreases. **Evista** simulates some of the supporting effects of estrogen at the postmenopausal stage.

Osteoporosis is a disease which causes a decrease in bone mass and increases the bones' tendency to fracture - this disease is especially common in postmenopausal women, although it is possible that initially no symptoms will appear. Osteoporosis increases the risk of bone fractures, especially those of the spinal column, hips and wrists, and may cause back pain, loss of height and a stooped posture.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are receiving, or had received in the past, treatment for blood clots in the legs (deep vein thrombosis), in the lungs (pulmonary embolism), or in the eyes (retinal vein thrombosis).
- You suffer, or have suffered in the past, from blood clots (thrombosis or thrombophlebitis) in the eyes, legs or lungs.
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see chapter 6 *"Additional information"*). Signs of allergic reaction include: rash, difficulties swallowing or breathing, swelling of the lips, face, throat or tongue.
- You are pregnant or can still become pregnant, since **Evista** may harm your fetus.

- You are breastfeeding.
- You expect to be immobile for a prolonged period of time.

Special warnings pertaining to the use of this medicine

Before starting treatment with Evista, tell your doctor if:

- You are immobilized, even for a certain period of time (e.g. restricted to a wheel chair, hospitalized or bedridden for the purpose of recovering from surgery or an unexpected illness), because this might increase the risk for blood clot formation (deep vein thrombosis, pulmonary embolism, or retinal vein embolism). Therefore, on long journeys/flights it is important to stand up and move around once in a while.
  Stop taking **Evista** at least 3 days (72 hours) prior to expected prolonged immobilization.
  Treatment with **Evista** should be resumed only after you are back on your feet and fully mobile again.
- Be alert for any troublesome signs and report to your doctor if you experience any of the following occurrences or any other sign that could indicate blood clots in the legs, lungs or eyes, such as: leg pain or a feeling of warmth in the calves; swelling of the legs, hands or feet.
  Sudden change in vision, such as blurred vision or loss of vision; sudden chest pain, shortness of breath or coughing up blood.
- You had a cerebrovascular accident (such as a stroke), or if your doctor told you that you are at high risk of experiencing a cerebrovascular accident.
- You suffer, or have suffered in the past, from impaired function of: the heart and/or blood vessels. If you suffer, or have suffered in the past, from congestive heart failure, irregular heartbeat, heart attack, or other illnesses that increase the risk for a heart attack. You must consult your doctor about the possible risks versus the benefits of the medicine.
- You suffer from a liver disease.
- You suffer, or have suffered in the past, from impaired function of the kidney or active cancer.
- There is a history of blood clots in your immediate family.
- You suffer, or have suffered in the past, from breast cancer, because there is not enough experience regarding the use of **Evista** in women who suffer from this disease.
- You are receiving oral estrogen treatment.
- You are sensitive to any food or medicine. You must inform your doctor before taking this medicine.

Evista does not cause breast tenderness or enlargement. Therefore, you must inform the doctor of any changes in your breasts. Likewise, you should not stop the routine follow-up recommended to you by your doctor.

Special warnings

It is unlikely for **Evista** to cause vaginal bleeding. Therefore, any vaginal bleeding while taking **Evista** is not to be expected, and in such an event you must contact your doctor immediately.

Evista is not used for treating postmenopausal symptoms such as hot flashes.

Evista reduces cholesterol levels and LDL ("bad" cholesterol) levels. It does not affect the levels of HDL ("good" cholesterol) or triglycerides; however, if you have taken estrogen in the past and experienced an abnormal increase in triglycerides levels, you must consult your doctor prior to taking **Evista**.

Drug interactions

If you are taking or have recently taken any other medicine, including over-the-counter medicines and nutritional supplements, inform your doctor or pharmacist. The doctor or pharmacist must be informed in particular if you are taking:

- Anticoagulants, such as coumadin preparations (warfarin) for the thinning of your blood; your doctor may need to adjust the dosage of these medications.

- Supplemental hormonal therapy or other systemic estrogens.

- High protein-bound drugs (e.g.: Diazepam, Diazoxide, Lidocaine). Concomitant use of one of these medicines with **Evista** may alter the concentration of these medicines in the blood.

- Cholestyramine and Colestipol. Medications used primarily for lowering serum lipid levels, because they affect **Evista** absorption from the digestive system and so lower the concentration of the medicine in the blood.

Use of this medicine and food
You may take **Evista** with or without food.

Pregnancy and lactation
Evista is intended for use by postmenopausal women only and not for women who can still become pregnant. **Evista** may harm your fetus, do not use it during pregnancy.
Do not take **Evista** if you are breastfeeding, because it might enter into the breast milk.

Driving and operating machinery
Evista does not affect or has negligible effect on driving and operating machinery.

Important information regarding some of the ingredients of the medicine
Evista contains lactose.
If your doctor told you that you are sensitive to lactose, a type of sugar, see your doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always use according to your doctor's orders.
You must check with your doctor or pharmacist if you are unsure.
The dosage and method of treatment will only be determined by your doctor.

The dosage is one tablet daily. It may be taken at any time during the day, but it will be easier for you to remember to take it if you take it at the same time every day. It may be taken with or without food.

Do not exceed the recommended dose

The tablet is intended to be taken orally.
Swallow the tablet whole. You can drink a glass of water with it if you want. Do not break or crush the tablet before taking it. The taste of a broken or crushed tablet may be unpleasant, and you might also receive an incorrect dosage.

It is possible that your doctor will recommend additional ways of preventing osteoporosis, such as: taking supplemental calcium or vitamin D tablets (in case their daily nutritional intake is insufficient).

If you accidentally took a higher dose
If you are taking a higher dosage of **Evista** than prescribed, you may experience muscle cramps in the legs and dizziness. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Evista at the specified time, do not take a double dose. Take the next dose at the usual time and consult your doctor.
Continue the treatment as instructed by your doctor.

If you stop taking Evista
Even if there is an improvement in your condition, do not discontinue treatment with this medicine without consulting your doctor or pharmacist.
It is important that you continue taking **Evista** for the entire period your doctor has prescribed this medicine.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any other questions regarding the use of this medicine, please consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of **Evista** may cause some side effects in some of its users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment and contact your doctor immediately if you experience the formation of blood clots in the veins (rare).

Common side effects (incidence of 1:100):

- Hot flashes (vasodilatation). **Evista** does not treat hot flashes. Over the first six months of treatment, you may even experience an increase in their frequency.
- Flu symptoms
- Swelling of the palms, feet and legs (peripheral oedema)
- Cramps in the muscles of the legs. These side effects usually disappear within a short time following the period of adaptation to the preparation.
- Gallstones

Uncommon side effects (incidence of 1:100 to1:1000):

- Increased risk of blood clots in the legs (deep vein thrombosis), discontinue treatment and contact your doctor immediately.
- Increased risk of blood clots in the lungs (pulmonary embolism), discontinue treatment and contact your doctor immediately.
- Increased risk of blood clots in the eyes (retinal vein thrombosis), discontinue treatment and contact your doctor immediately.
- The skin around the vein is red and painful (superficial vein thrombophlebitis)
- Arterial blood clot (e.g. stroke, including an increased risk to die from a stroke)
- A decrease in the amount of blood platelets

If any of the side effects gets worse, or if you are suffering from a side effect that has not been mentioned in this leaflet, consult a doctor.

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and all other medicines must be stored in a secured place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiration date (exp. date) appearing on the package. The expiration date refers to the last day of that month.

Storage conditions: Store at a temperature below 25°C.

Store in the original package.

Do not flush medicines down the drain or discard them in the trash. Ask your pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Tablet core: Povidone, polysorbate 80, anhydrous lactose, lactose monohydrate, crospovidone K-30, magnesium stearate.

Tablet coating: Titanium dioxide (E 171), polysorbate 80, hypromellose, macrogol 400, carnauba wax.

Color: n-Butyl alcohol, isopropyl alcohol, ammonium hydroxide, pharmaceutical glaze, propylene glycol, indigo carmine (E 132).

The medicine's appearance and the contents of the package:
Evista is a white oval coated tablet, marked with the number 4165. **Evista** tablets are packaged in an aluminum blister. **Evista** tablets are supplied in packages of 14 or 28 tablets.

Manufacturer name and address: Lilly S.A., Alcobendas (Madrid), Spain.

License holder and address: Eli Lilly Israel Ltd., P.O.Box 2160, Herzliya Pituach 46120

This leaflet was checked and approved by the Ministry of Health in December 2013.
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