

# EVISTA<sup>®</sup> TABLET

Raloxifene hydrochloride (60mg)

## What is in this leaflet

1. What Evista is used for
2. How Evista works
3. Before you use Evista
4. How to use Evista
5. While you are using it
6. Side Effects
7. Storage and Disposal of Evista
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Evista is used for

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 is not for use in premenopausal women. Evista is also use for the reduction of the risk of invasive breast cancer in postmenopausal women.

## How Evista works

Evista contains the active ingredient raloxifene hydrochloride. Evista belongs to a group of non-hormonal medicines called selective oestrogen receptor modulators (SERMs). 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. It also works to decrease the risk of invasive breast cancer by blocking estrogen in breast and uterine tissue.

## Before you use Evista

### - When you must not use it

You should not take Evista if you:

- Are allergic to raloxifene or any of the other ingredients of this

medicine. (see section **Product description**).

- Are pregnant or could become pregnant. Evista could harm your unborn child.
- Are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.
- 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. Have liver disease (including cholestasis [any condition in which the flow of bile from the liver is slowed or blocked]).
- Have severe kidney problems.
- Have any unexplained vaginal bleeding. This must be investigated by your doctor.
- Have active uterine cancer, as there is insufficient experience of raloxifene hydrochloride use in women with this disease.

### - Before you start to use it

Before you take Evista, tell your doctor 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).
- Are or known you will be immobilised for some time, e.g., being wheelchair bound or having to stay in bed while

recovering from an operation or illness.

- Are on oestrogen or hormone replacement therapy (HRT).
- Have had breast cancer. Evista has not been fully studied in women who have a history of breast cancer.
- Have liver or kidney problems.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- Any form of estrogen therapy that comes as a pill, patch or injection.
- Cholestyramine or other anion exchange resins to lower blood lipids.
- 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 and may need to adjust the dose of your warfarin or other coumarin blood thinner.

Other medicines not listed above may also interact with Evista. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## How to use Evista

### - How much to use

Take one Evista tablet each day with or without food.

Your doctor may advise you to take Evista with calcium and vitamin D. Your doctor will tell you how much you should take each day. Calcium and/ or

# EVISTA<sup>®</sup> TABLET

Raloxifene hydrochloride (60mg)

vitamin may be taken at the same time as Evista.

- When you use it

It does not matter what time of day you take your tablet.

However, it is best to take it at the same time each day as this will help you remember to take it.

- How long to use it

Continue taking Evista for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose. Do not take 2 doses at the same time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

In *adults*, symptoms of an overdose may include leg cramps and dizziness.

In *children*, symptoms of an overdose may include coordination problems, dizziness, vomiting, rash, diarrhoea, repetitive shaking, and flushing.

### While you are using it

- Things you must do

- Remember to take Evista daily and at the dose prescribed by your doctor
- If you are going on a long plane or car trip, you should move about

periodically.

Tell your doctor if you

- Become pregnant while taking Evista
- Are immobilised for some time
- Have any vaginal bleeding.

- Things you must not do

- Do not stop taking Evista without first checking with your doctor.
- Do not give Evista to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- 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.
- Do not use Evista to prevent heart disease, heart attack or strokes.
- Women who have hot flushes can take Evista. However, Evista does not treat hot flushes, and it may cause hot flushes in some women
- 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.

### Side effects

The more common side effects of Evista include:

- Hot flushes, common first 6 months after starting

- Leg cramps
- Muscle spasms
- Swelling of hands, feet and legs
- Flu-like symptoms

Tell your doctor right away or go to the nearest hospital if you notice any of the following:

- Severe pain or swelling in your legs
- Severe stomach pain
- Sudden chest pain, shortness of breath or coughing up blood
- Sudden change in your vision, such as loss of vision or blurred vision

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Evista. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

### Storage and Disposal of Evista

- Storage

Keep out of reach and sight of children. Do not store Evista above 25°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### Product Description

- What it looks like

# EVISTA<sup>®</sup> TABLET

Raloxifene hydrochloride (60mg)

---

Evista is supplied as tablets that are white, film-coated and oval shaped with imprinted code 4165.

- Ingredients

- Active ingredient  
Raloxifene hydrochloride.

- Inactive ingredients

*Tablet core:* Povidone, polysorbate 80, anhydrous lactose, lactose monohydrate, crospovidone, magnesium stearate.

*Tablet coating:* titanium dioxide (E171), polysorbate 80, hypromellose, macrogol 400, carnauba wax.

*Ink:* shellac, propylene glycol, indigo carmine (E132).

- MAL Number

MAL04125481A

**Manufacturer**

Lilly, S.A  
Avda. De la Industria, 30  
28108 Alcobendas, Madrid  
Spain

**Product Registration Holder**

Takeda Malaysia Sdn Bhd  
Unit TB-L13-1, Level 13,  
Tower B, Plaza 33,  
No. 1, Jalan Kemajuan,  
Seksyen 13,  
46200 Petaling Jaya, Selangor,  
Malaysia.

**Date of Revision**

26/11 /2015

**Serial Number**

BPFK (R4/1)181115/00434