I. NAME OF PRODUCT

EVISTA® tablets 60mg

II. DESCRIPTION OF PRODUCT

EVISTA® tablets are white, oval shaped and film coated. Each EVISTA® tablet has the identicode number '4165' printed on it in blue ink. Each tablet of EVISTA® contains 60mg of the active ingredient called Raloxifene.

The tablet also contains:

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

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

Ink: Shellac, propylene glycol, indigo carmine (E 132).

III. WHAT IS THE MEDICINE?

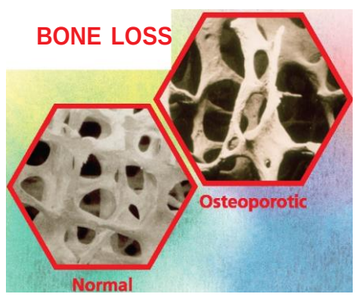
EVISTA® belongs to a group of non-hormonal medicines called Selective Estrogen Receptor Modulators. When a woman reaches menopause, the level of the female sex hormone, oestrogen, goes down. EVISTA® mimics some of the beneficial effects of oestrogen after menopause.

Estrogen is a female hormone that affects your bones as well as other parts of the body.

With the onset of menopause, a woman's body produces up to 80% less[1] estrogen. A reduction in estrogen has a high impact on bones. It causes bones to become thinner and weaker and may result in a condition called osteoporosis.

Osteoporosis is especially common in women after menopause. While osteoporosis may have no symptoms at first, it makes your bones more likely to break, especially in your spine, hips and wrists. Osteoporosis may also cause back pain, loss of height and a curved back.

Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone.



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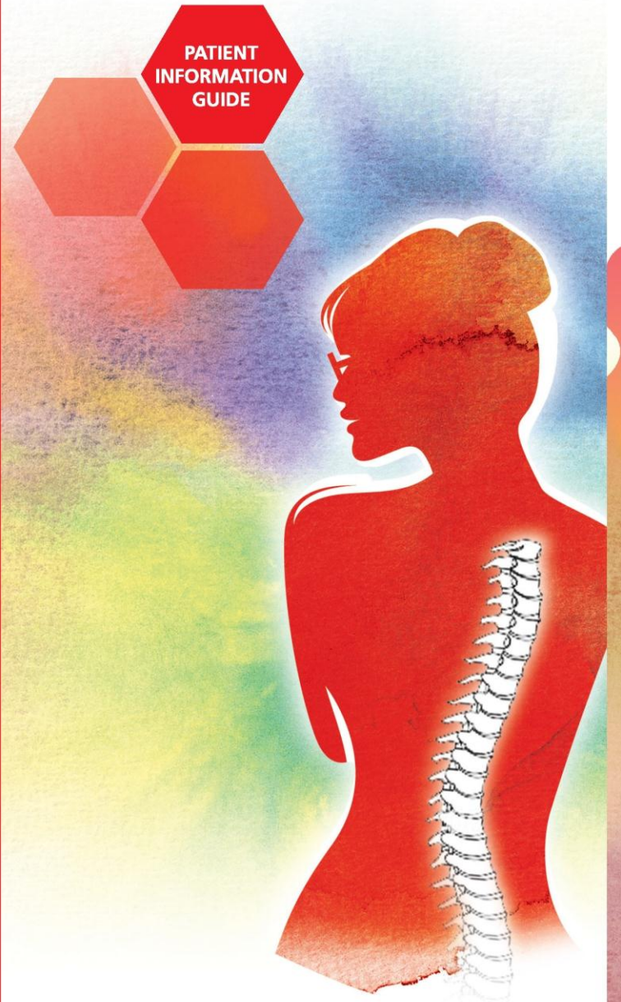
TAKEDA PHARMACEUTICALS
(ASIA PACIFIC) PTE. LTD.

PATIENT INFORMATION GUIDE



EVISTA
Raloxifene HCl

Your doctor has recommended EVISTA® (raloxifene HCl) for you. This leaflet will provide answers to some common questions about this medicine, to better understand how EVISTA® can help you cope with the effects of menopause. It does not contain all the available information and does not take the place of talking with your doctor.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

EVISTA® is available only with doctor's prescription. If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with this medicine. You may need to read it again.

IV. WHAT IS THIS MEDICINE USED FOR?

EVISTA® is used to prevent and treat osteoporosis in women after menopause.

EVISTA® is also used to reduce the risk of invasive breast cancer in women with osteoporosis after menopause.

V. HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

The usual dose of EVISTA® is one tablet per day.

EVISTA® tablets should be swallowed whole with a glass of water. You may take EVISTA® with or without food and you don't have to stay upright after taking it. When prescribed for the treatment or prevention of osteoporosis, EVISTA® should be taken in conjunction with supplementary calcium if daily calcium intake is inadequate.

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.

For maximum benefit, EVISTA® is intended for long-term use.

Do not stop taking EVISTA® without first talking to your doctor.

VI. WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- if you have not been through menopause. EVISTA® is only for use by women after menopause and must not be taken by women who could still have a baby.
- if you have had an allergic reaction to EVISTA® or any of the ingredients listed at the beginning of this leaflet (see 'DESCRIPTION OF THE PRODUCT'). Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- if you are being treated or have been treated for blood clots.
- if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right.
- if the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.
- Hepatic impairment including cholestasis.
- Severe renal impairment.
- Unexplained uterine bleeding.
- Patients with signs or symptoms of endometrial cancer.

VII. SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you experience any effect or feel unwell while you are taking EVISTA®.

Unwanted side effects vary from patient to patient but most of the side effects seen with EVISTA® have been mild.

Like all medicines, this medicine can cause side effects although not everybody gets them. The majority of side effects seen with EVISTA® have been mild.

The most common side effects (affects more than 1 user in 10) are:

- Hot flushes (vasodilatation)
- Flu syndrome
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain and stomach upset
- Increased blood pressure

Common side effects (affects 1 to 10 users in 100) are:

- Leg cramps
- Swelling of hands, feet and legs (peripheral oedema)
- Headache including migraine
- Rash
- Mild breast symptoms such as pain, enlargement and tenderness

Uncommon side effects (affects 1 to 10 users in 1000) are:

- Increased risk of blood clots in the legs (deep vein thrombosis)
- Increased risk of blood clots in the lungs (pulmonary embolism)
- Increased risk of blood clots in the eyes (retinal vein thrombosis)
- Skin around the vein is red and painful (superficial vein thrombophlebitis)
- Fatal strokes
- Blood clot in an artery (arterial thromboembolic reaction)
- Increased risk of blood clots in the veins (venous thromboembolic reaction)
- Decrease in the number of the platelets in the blood (Thrombocytopenia)

Rare side effects are

Very rare side effects are

-

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

VIII. WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILST TAKING THIS MEDICINE?

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and EVISTA® may interfere with each other. These include:

- medicines for your heart such as digitalis drugs (e.g. digoxin) or blood thinning drugs such as warfarin. Your doctor may need to adjust the dose of these medicines.
- hormone replacement therapy **(HRT)** or estrogens.
- lipid-lowering drugs including cholestyramine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking EVISTA®.

Tell your doctor about these things before taking EVISTA®.

IX. WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If it is almost time for your next dose, skip the tablet you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

X. HOW SHOULD YOU KEEP THIS MEDICINE?

Keep your tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 30°C.

All medicines should be kept where young children cannot reach them.

There will be an expiry date (month.year) on your EVISTA® pack. The medicine should not be taken after this date because it may have lost some of its strength.

XI. SIGNS & SYMPTOMS OF OVERDOSE

Symptoms of an overdose may include leg cramps and dizziness.

XII. WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you notice any of the symptoms or even if there are no signs of discomfort or poisoning please contact your doctor if you have taken more than the recommended dosage.

XIII. CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

Do not stop taking EVISTA® without first checking with your doctor.

Do not give EVISTA® to anyone else, your doctor has prescribed it specifically for you.

It is important that you remember to take EVISTA® daily and at the dose prescribed by your doctor.

Tell all doctors and pharmacists who are treating you that you are taking EVISTA®.

While you are taking EVISTA®, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking EVISTA®, tell your doctor.

Tell your doctor if you are immobilised for some time, e.g., being wheel-chair bound or having to stay in bed while recovering from an operation or illness.

If you are going on a long plane or car trip, you should move about periodically.

Tell your doctor if you have any vaginal bleeding.

Before you start taking EVISTA®, you must tell your doctor:

- if you have any unexplained vaginal bleeding.
- if you are at risk of blood clots.
- if you are, or know you will be immobilised for some time, e.g., being wheel-chair bound or having to stay in bed while recovering from an operation or illness.
- if you have liver disease.
- if you are intolerant of lactose. EVISTA® contains a small amount of lactose (about 150 mg) which is unlikely to affect you.
- if you have menopausal symptoms, such as hot flushes. EVISTA® does not treat hot flushes.
- if you are breastfeeding.
- if you are on estrogen or hormone replacement therapy (HRT).
- if you have or have had high blood fats (triglycerides) caused by estrogen.
- if you have previously had a stroke, or if you have ever had other risk factors for stroke such as a mini-stroke (transient ischaemic attack) or a type of irregular heartbeat called atrial fibrillation.
- if you have had breast cancer.

EVISTA® is not intended to be taken by men.

EVISTA® has no known effect on driving or the ability to use machinery.

XIV. NAME OF MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by:
Lilly, S.A.
Avda. de la Industria, 30
28108 Alcobendas (Madrid), Spain

Product licence holder:
Takeda Pharmaceuticals (Asia Pacific) Pte. Ltd.
21 Biopolis Road
Nucleos North Tower, Level 4
Singapore 138567

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