

Package leaflet: Information for the user

Evista 60 mg film coated tablets
raloxifene hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Evista is and what it is used for
2. What you need to know before you take Evista
3. How to take Evista
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1. What Evista is and what it is used for

Evista contains the active substance raloxifene hydrochloride.

Evista is used to treat and prevent osteoporosis in postmenopausal women. Evista reduces the risk of vertebral fractures in women with postmenopausal osteoporosis. A reduction in the risk of hip fractures has not been shown.

How Evista works

Evista belongs to a group of non-hormonal medicines called Selective Oestrogen Receptor Modulators (SERMs). When a woman reaches the menopause, the level of the female sex hormone oestrogen goes down. Evista mimics some of the helpful effects of oestrogen after the menopause.

Osteoporosis is a disease that causes your bones to become thin and fragile - this disease is especially common in women after the menopause. Although it may have no symptoms at first, osteoporosis makes you more likely to break bones, especially in your spine, hips and wrists and may cause back pain, loss of height and a curved back.

2. What you need to know before you take Evista

Do not take Evista:

- If you are being treated or have been treated for blood clots in the legs (deep vein thrombosis), in the lungs (pulmonary embolism) or in the eyes (retinal vein thrombosis).
- If you are allergic (hypersensitive) to raloxifene or any of the other ingredients of this medicine (listed in section 6).
- If there is still a possibility that you can get pregnant, Evista could harm your unborn child.
- If you have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestatic jaundice).
- If you have severe kidney problems.
- If you have any unexplained vaginal bleeding. This must be investigated by your doctor.

- If you have active uterine cancer, as there is insufficient experience of Evista use in women with this disease.

Warnings and precautions

Talk to your doctor or pharmacist before you take Evista.

- If you are immobilised for some time such as being wheel-chair bound, needing to be admitted to a hospital or having to stay in bed while recovering from an operation or an unexpected illness as these may increase your risk of blood clots (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis).
- If you have had a cerebrovascular accident (e.g. stroke), or if your doctor has told you that you are at high risk of having one.
- If you have liver disease
- If you are suffering from breast cancer, as there is insufficient experience of Evista use in women with this disease.
- If you are receiving oral oestrogen therapy.

It is unlikely that Evista will cause vaginal bleeding. So any vaginal bleeding while you take Evista is unexpected. You should have this investigated by your doctor.

Evista does not treat postmenopausal symptoms, such as hot flushes.

Evista lowers total cholesterol and LDL ("bad") cholesterol. In general, it does not change triglycerides or HDL ("good") cholesterol. However, if you have taken oestrogen in the past and had extreme elevations in triglycerides, you should talk to your doctor before taking Evista.

Evista contains lactose

If you have been told by your doctor that you have an intolerance to lactose, a type of sugar, contact your doctor before taking this medicinal product.

Other medicines and Evista

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking digitalis medicines for your heart or anticoagulants like warfarin to thin your blood, your doctor may need to adjust your dose of these medicines.

Tell your doctor if you are taking cholestyramine which is mainly used as lipid-lowering medicine, because Evista may not work as well.

Pregnancy and breast-feeding

Evista is for use only by postmenopausal women and must not be taken by women who could still have a baby. Evista could harm your unborn child.

Do not take Evista if you are breast-feeding as it might be excreted in mother's milk.

Driving and using machines

Evista has no or negligible effects on driving or using machines.

3. How to take Evista

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose is one tablet a day. It does not matter what time of day you take your tablet but taking the tablet at the same time each day will help you remember to take it. You may take it with or without food.

The tablets are for oral use.

Swallow the tablet whole. If you wish you may take a glass of water with it. Do not break or crush the tablet before taking it. A broken or crushed tablet may taste bad and there is a possibility that you will receive an incorrect dose.

Your doctor will tell you how long you should continue to take Evista. The doctor may also advise you to take calcium and vitamin D supplements.

If you take more Evista than you should

Tell your doctor or pharmacist. If you take more Evista than you should you could have leg cramps and dizziness.

If you forget to take Evista

Take a tablet as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten tablet dose.

If you stop taking Evista

You should talk to your doctor first.

It is important that you continue taking Evista for as long as your doctor prescribes the medicine.

Evista can treat or prevent your osteoporosis only if you continue to take the tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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:

- Headache including migraine
- Leg cramps
- Swelling of hands, feet and legs (peripheral oedema)
- Gallstones
- 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)
- Blood clot in an artery (for example stroke, including an increased risk of dying from stroke)
- Decrease in the number of the platelets in the blood

In rare cases, blood levels of liver enzymes may increase during treatment with Evista.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: **Ireland:** HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie e-mail: medsafety@hpra.ie **United Kingdom:** Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store, **Malta:** ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Evista

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.

Store in the original package. Do not freeze.

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.

6. Contents of the pack and other information

What Evista contains

- The active substance is raloxifene hydrochloride. Each tablet contains 60 mg of raloxifene hydrochloride, which is equivalent to 56 mg raloxifene.
- The other ingredients are:

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).

What Evista looks like and contents of the pack

Evista are white, oval, film coated tablets which are marked with the number 4165. They are packed in blisters or in plastic bottles. The blister boxes contain 14, 28 or 84 tablets. The bottles contain 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Daiichi Sankyo Europe GmbH, Zielstattstrasse 48, D-81379 Munich, Germany.

Manufacturer

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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/ Belgien

Daiichi Sankyo Belgium N.V.-S.A
Tél/Tel: +32-(0) 10 48 95 95

България

Daiichi Sankyo Europe GmbH
Тел.: +49-(0) 89 7808 0

Česká republika

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Danmark

Daiichi Sankyo Europe GmbH
Tlf: +49-(0) 89 7808 0

Deutschland

Daiichi Sankyo Deutschland GmbH
Tel: +49-(0) 89 7808 0

Eesti

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Ελλάδα

Φαρμασερβ-Λίλλυ Α.Ε.Β.Ε.
Τηλ: +30 210 629 4600

España

Daiichi Sankyo España, S.A.
Tel: +34 91 539 99 11

France

Daiichi Sankyo France S.A.S.
Tél: +33-(0) 1 55 62 14 60

Hrvatska

Medis Adria d.o.o.
Tel: +385-(0) 1 230 34 46

Ireland

Daiichi Sankyo Ireland Ltd
Tel: +353-(0) 1 489 3000

Ísland

Daiichi Sankyo Europe GmbH
Simi: +49-(0) 89 7808 0

Italia

Daiichi Sankyo Italia S.p.A.
Tel: +39-06 85 2551

Κύπρος

Phadisco Ltd.
Τηλ: +357 22 715000

Latvija

Daiichi Sankyo Europe GmbH
Tel.: +49-(0) 89 7808 0

Lietuva

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Luxembourg/Luxemburg

Daiichi Sankyo Belgium N.V.-S.A
Tél/Tel: +32-(0) 10 48 95 95

Magyarország

Goodwill Pharma Kft.
Tel: +36 62 443 571

Malta

Charles de Giorgio Ltd.
Tel: +356 25600 500

Nederland

Daiichi Sankyo Nederland B.V.
Tel: +31-(0) 20 4 07 20 72

Norge

Daiichi Sankyo Europe GmbH
Tlf: +49-(0) 89 7808 0

Österreich

Daiichi Sankyo Austria GmbH
Tel: +43-(0) 1 485 86 42 0

Polska

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Portugal

Daiichi Sankyo Portugal, Unip., Lda.
Tel: +351 21 4232010

România

Terapia SA
Tel: +40-(0) 26 45 01 502

Slovenija

Medis, d.o.o.
Tel: +386 1 589 69 00

Slovenská republika

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

Suomi/Finland

Daiichi Sankyo Europe GmbH
Puh./Tel: +49-(0) 89 7808 0

Sverige

Daiichi Sankyo Europe GmbH
Tel: +49-(0) 89 7808 0

United Kingdom

Daiichi Sankyo UK Ltd
Tel: +44-(0) 1753 893 600

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.ema.europa.eu>