**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

**BOTTLE LABEL, BOTTLE CARTON:**

## 1. NAME OF THE MEDICINAL PRODUCT

EVISTA 60 mg film coated tablets
raloxifene hydrochloride

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film coated tablet contains 60 mg raloxifene hydrochloride, equivalent to 56 mg raloxifene

## 3. LIST OF EXCIPIENTS

Also includes lactose

See leaflet for further information

## 4. PHARMACEUTICAL FORM AND CONTENTS

100 film coated tablets

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

EXP {MM/YYYY}

## 9. SPECIAL STORAGE CONDITIONS

Store in the original package.
Do not freeze.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SUBSTIPHARM
24 rue Erlanger
75016 Paris
France

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/073/004

## 13. BATCH NUMBER

Batch {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Evista

## 17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

## 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**BLISTER BOX FILM COATED TABLETS:**

## 1. NAME OF THE MEDICINAL PRODUCT

EVISTA 60 mg film coated tablets
raloxifene hydrochloride

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film coated tablet contains 60 mg raloxifene hydrochloride, equivalent to 56 mg raloxifene

## 3. LIST OF EXCIPIENTS

Also includes lactose

See leaflet for further information

## 4. PHARMACEUTICAL FORM AND CONTENTS

14 film coated tablets
28 film coated tablets
84 film coated tablets

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

EXP {MM/YYYY}

## 9. SPECIAL STORAGE CONDITIONS

Store in the original package. Do not freeze.

## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

## 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SUBSTIPHARM
24 rue Erlanger
75016 Paris
France

## 12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/073/001 14 film coated tablets
EU/1/98/073/002 28 film coated tablets
EU/1/98/073/003 84 film coated tablets

## 13. BATCH NUMBER

Batch {number}

## 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

## 15. INSTRUCTIONS ON USE

## 16. INFORMATION IN BRAILLE

Evista

## 17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

## 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER (ALL BLISTER PACKS):**

## 1. NAME OF THE MEDICINAL PRODUCT

EVISTA 60 mg film coated tablets
raloxifene hydrochloride

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

SUBSTIPHARM

## 3. EXPIRY DATE

EXP {MM/YYYY}

## 4. BATCH NUMBER

Lot {number}

## 5. OTHER

**B. PACKAGE LEAFLET**

**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

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 the national reporting system listed in Appendix V. 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**
SUBSTIPHARM, 24 rue Erlanger, 75016 Paris, France.

**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:

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**This leaflet was last revised in month YYYY.**

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