PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EVISTA 60 mg tablets

Read this information before you start taking EVISTA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- EVISTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 povidone, polysorbate 80, anhydrous lactose, lactose monohydrate, crospovidone, magnesium stearate, titanium dioxide (E 171), hypromellose, macrogol 400, carnauba wax, shellac, propylene glycol, indigo carmine (E 132).

WHAT EVISTA IS USED FOR:

- EVISTA belongs to a group of non-hormonal medicines called Selective Estrogen Receptor Modulators (SERMs). When a woman reaches menopause, the level of the female sex hormone oestrogen goes down. EVISTA mimics some of the helpful effects of oestrogen after menopause.
- EVISTA is used to reduce the risk of development of invasive breast cancer in postmenopausal women with osteoporosis. The risk reduction is not applicable to oestrogen receptor negative (ER-) cancers or cancers of unknown oestrogen receptor status.

- EVISTA is indicated for the prevention and treatment of 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.

BEFORE YOU TAKE EVISTA:

Do not take EVISTA if you:

- Could still have a baby.
- Are being treated or have been treated for blood clots (deep vein thrombosis, pulmonary embolism or retinal (in the eye) vein thrombosis).
- Have had an allergic reaction in the past to EVISTA or to any of the other ingredients listed at the beginning of this leaflet.
- Have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestatic jaundice).
- Have unexplained vaginal bleeding. Your doctor must investigate this.
- Have active uterine cancer, as there is insufficient experience of EVISTA use in women with this disease.
- Have severe renal/kidney impairment.

Take special care with EVISTA:

Talk to your doctor before taking EVISTA if you:

- Are immobilised for some time such as being wheel chair bound, needing to be admitted to hospital or having to stay in bed while recovering from an operation or an unexpected illness.
- Are on hormone replacement therapy (HRT) or take any other systemic oestrogens.

Other considerations:

- It is unlikely that EVISTA will cause vaginal bleeding. So any vaginal bleeding while you take EVISTA is unexpected and should be investigated by your doctor.
- EVISTA does not treat postmenopausal symptoms, such as hot flushes.
- If you have taken oestrogen in the past and had extreme elevations in triglycerides, you should talk to your doctor before taking EVISTA.

Taking EVISTA with food and drink:

- EVISTA may be taken with or without food

Pregnancy and breastfeeding

- EVISTA is for use only by postmenopausal women and must not be taken by women who could still have a baby.
- Do not take EVISTA if you are breastfeeding as it might be excreted in mother's milk.

Driving and using machinery:

EVISTA has no known effects on driving or using machinery.

Important information about other ingredients of EVISTA:

EVISTA contains lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Evista.

Taking other medicines with EVISTA:

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of EVISTA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.
- 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.
- Cholestyramine affects EVISTA by limiting its absorption. Cholestyramine is mainly used as lipid lowering medicine.

HOW TO TAKE EVISTA:

- The tablets are for oral use.
- The dose is one tablet a day. It does not matter what time of the 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.
- Swallow the tablet whole. You may take a glass of water with it.

- Always take EVISTA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- Your doctor will tell you how long you should continue to take EVISTA. The doctor might also advise you to take calcium and vitamin D supplements.
- Do not stop taking EVISTA without talking to your doctor first.
- **If you forget to take EVISTA:** take a tablet as soon as you remember and then continue as before.
- If you take more tablets than your doctor prescribed: tell your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

- EVISTA can have side effects. Venous thrombo-embolic events (including deep vein thrombosis (DVT), pulmonary embolism, retinal vein thrombosis), and superficial vein thrombophlebitis were observed rarely
- The occurrence of hot flushes (vasodilatation) may be increased in EVISTA patients when compared to those not treated with it.
- The hot flushes were usually noticed in the first 6 months of treatment, and seldom occurred for the first time afterwards.
- Other common side effects are leg cramps and swelling of hands, feet and legs (peripheral oedema).
- Blood levels of liver enzymes may increase during treatment with EVISTA.
- The following side effects have been reported (less than 1 in every 10 000 patients) by patients taking EVISTA: rash, gastrointestinal symptoms such as nausea, vomiting, abdominal pain and dyspepsia; increased blood pressure; headache including migraine; and mild breast symptoms such as pain, enlargement and tenderness.

Not all side effects reported for EVISTA are included in this leaflet. Should your general health worsen while taking EVISTA, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSING OF EVISTA:

Store all medicines out of reach of children.

- Store at or below 30 °C. Store in original package. Do not freeze.
- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF EVISTA:

EVISTA 60 mg Tablets are supplied in blister packs of 28. The blister pack consists of PVC/PE/PCTFE blisters with aluminium foil lidding.

IDENTIFICATION OF EVISTA:

EVISTA Tablets, are white, film-coated, elliptically shaped tablets, which are imprinted with 4165 in blue ink.

REGISTRATION NUMBERS/ REFERENCE NUMBERS:

EVISTA 60 mg (Tablets): **32/34/0423**

NAME AND ADDRESS OF REGISTRATION HOLDER:

Eli Lilly (S.A.) (Pty) Limited

Golden Oak House, Ballyoaks Office Park

35 Ballyclare Drive

Bryanston, 2191

DATE OF PUBLICATION:

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PASIËNTINLIGTINGSBROSJURE

SKEDULERINGSTATUS: S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

EVISTA 60 mg tablette

Lees hierdie inligting voordat jy begin om EVISTA te neem.

- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker daaroor.
- EVISTA is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander persone te deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT EVISTA BEVAT:

- Die aktiewe bestanddeel is raloksifeenhidrochloried. Elke tablet bevat 60 mg raloksifeenhidrochloried, wat aan 56 mg raloksifeen ekwivalent is**.**
- Die ander bestanddele is povidoon, polisorbaat 80, anhidriese laktose, laktosemonohidraat, krospovidoon, magnesiumstearaat, titaandioksied (E 171), hipromellose, makrogol 400, carnoubawas, skellak, propileenglikol, indigo-karmosyn (E 132).

WAARVOOR EVISTA GEBRUIK WORD:

- EVISTA behoort aan ‘n groep nie-hormonale medisyne wat as Selektiewe Estrogeenreseptor-Moduleerders (SERMs) bekendstaan. Wanneer ‘n vrou die menopouse bereik, daal die vlak van estrogeen, die vroulike sekshormoon. Na die menopouse, boots EVISTA sommige van die nuttige effekte van estrogeen na.

- EVISTA word gebruik om die risiko van die ontwikkeling van indringende borskanker in postmenopousale vrouens met osteoporose te verminder. Die risikovermindering is nie van toepassing op estrogeenreseptor-negatiewe (ER-) kankers of kankers van onbekende estrogeenreseptorstatus.

- EVISTA word aangedui vir die voorkoming en behandeling van osteoporose in postmenopousale vrouens. EVISTA verminder die risiko van vertebrale frakture by vrouens met postmenopousale osteoporose. ‘n Vermindering in die risiko van heup frakture is nie gedemonstreer nie.

VOORDAT JY EVISTA NEEM:

Moenie EVISTA neem nie, indien jy:

- Nog ‘n baba kan hê.
- Behandel word of in die verlede, behandel is vir bloedklonte (diepvenatrombose, pulmonale embolisme of trombose van die retinale (in die oog) vene.
- In die verlede ‘n allergiese reaksie gehad het teen EVISTA of enigeen van die ander bestanddele wat aan die begin van hierdie brosjure gelys word.
- Lewersiekte het (voorbeelde van lewersiekte sluit sirrose, ligte hepatiese inkorting of cholestatiese geelsug, in).
- Onverklaarde vaginale bloeding het. Jou dokter moet dit ondersoek.
- Aktiewe kanker van die uterus het, omdat daar onvoldoende ondervinding met die gebruik van EVISTA by vrouens met hierdie siekte beskikbaar is.
- Ernstige renale/ nierinkorting het.

Neem spesiale sorg met EVISTA:

Vertel jou dokter voordat jy EVISTA neem, indien jy:

- Vir ‘n tydperk geïmmobiliseer moet word soos om rolstoel-gebonde te moet wees, in ‘n hospitaal opgeneem moet word, of in die bed moet bly terwyl jy van ‘n operasie of ‘n onverwagse siekte herstel.
- Op hormoonvervangingsterapie (HVT) is of enige ander sistemiese estrogene neem.

Ander oorwegings:

- Dit is onwaarskynlik dat EVISTA vaginale bloeding sal veroorsaak. Dus is enige vaginale bloeding terwyl jy EVISTA neem, onverwags en behoort dit deur jou dokter ondersoek te word.
- EVISTA behandel nie postmenopousale simptome soos warm gloede nie.
- Indien jy in die verlede estrogeen geneem het en uitermatige verhogings in trigliseriede gehad het, behoort jy met jou dokter daaroor te gesels voordat jy EVISTA neem.

Neem van EVISTA saam met kos en drank:

- EVISTA kan met, of sonder, voedsel geneem word.

Swangerskap en borsvoeding:

- EVISTA is alleenlik vir gebruik deur postmenopousale vrouens bedoel en moet nie geneem word nie deur vrouens wat moontlik nog ‘n baba kan hê.
- Moenie EVISTA neem nie indien jy borsvoed omdat dit in moedersmelk uitgeskei mag word.

Bestuur en gebruik van masjiene:

EVISTA het geen bekende effekte op bestuur of die gebruik van masjiene nie.

Belangrike inligting oor ander bestanddele van EVISTA:

EVISTA bevat laktosemonohidraat. Indien jou dokter vir jou vertel het dat jy ‘n intoleransie teen sommige suikers het, moet jy jou dokter kontak voordat jy EVISTA neem.

Neem van ander medisyne saam met EVISTA:

- Indien jy ander medisyne gereeld neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van EVISTA saam met hierdie medisynes ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies.
- Indien jy digitalismedisyne neem vir jou hart of antikoagulante soos warfarien om jou bloed te verdun, sal jou dokter moontlik jou dosis van hierdie medisyne moet aanpas.
- Cholestiramien affekteer EVISTA deur beperking van die absorpsie daarvan.

Cholestiramien word hoofsaaklik as ‘n lipied-verlagende medisyne gebruik.

HOE OM EVISTA TE NEEM:

- Die tablette is vir orale gebruik.
- Die dosis is een tablet per dag. Dit maak nie saak op watter tyd van die dag jy jou tablet neem nie, maar die inname van die tablet op dieselfde tyd elke dag sal jou help om te onthou om dit te neem. Jy mag dit met, of sonder, voedsel neem.

- Sluk die tablet heel in. Jy mag ‘n glas water daarmee drink.

- Jy moet EVISTA altyd presies volgens jou dokter se instruksies neem. Jy moet met jou dokter of apteker gesels indien jy onseker is.

- Jou dokter sal vir jou vertel hoe lank jy moet voortgaan om EVISTA te neem. Die dokter sal moontlik ook vir jou aanraai om kalsium- en vitamien D-aanvullings te neem.

- Moenie inname van EVISTA staak nie, sonder om eers met jou dokter te gesels.

- **Indien jy vergeet om EVISTA te neem**: neem ‘n tablet sodra jy onthou en gaan dan voort soos vantevore.

- Indien jy meer tablette neem as wat jou dokter voorgeskryf het: vertel jou dokter of apteker daarvan.

MOONTLIK NEWE-EFFEKTE:

- EVISTA kan newe-effekte veroorsaak. Veneuse tromboëmboliese insidente (insluitend diepvenatrombose (DVT), pulmonale embolisme, trombose van die retinale vene), en oppervlakkige tromboflebitis van die vene word selde waargeneem.
- Die voorkoms van warm gloede (vasodilatasie) mag verhoog wees in EVISTA-pasiënte as hulle met pasiënte wat nie daarmee behandel word, vergelyk word.

- Die warm gloede is gewoonlik waargeneem gedurende die eerste 6 maande van behandeling, en het selde vir die eerste keer daarna voorgekom.
- Ander algemene newe-effekte is beenkrampe en swelling van die hande, voete en bene (perifere edeem).
- Bloedvlakke van lewerensieme mag gedurende behandeling met EVISTA toeneem.
- Die volgende newe-effekte is aangemeld (in minder as 1 uit elke 10 000 pasiënte) deur pasiënte wat EVISTA geneem het: veluitslag, gastroïntestinale simptome soos naarheid, braking, abdominale pyn en dispepsie; verhoogde bloeddruk; hoofpyn insluitend migraine; en ligte borssimptome soos pyn, vergroting en teerheid.

Nie alle newe-effekte wat vir EVISTA aangemeld is, word in hierdie brosjure ingesluit nie.
Indien jou algemene gesondheid sou vererger terwyl jy hierdie medisyne neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

OPBERGING EN WEGDOENING VAN EVISTA:

Bewaar alle medisyne buite bereik van kinders.

- Bewaar by of onder 30 °C. Bewaar in die oorspronklike verpakking. Moenie vries nie.
- Moenie na die vervaldatum wat op die verpakking genoem word, gebruik nie.
- Gee alle ongebruikte medisyne terug aan jou apteker. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN EVISTA:EVISTA 60 mg Tablette word in stulpverpakkings van 28 verskaf. Die stulpverpakking bestaan uit PVC/PE/PCTFE-blasies met ‘n aluminiumfoelie bedekking.

IDENTIFIKASIE VAN EVISTA:

EVISTA Tablette is wit, filmbedekte, ellipties-gefatsoeneerde tablette wat met 4165 in blou ink bedruk is.

REGISTRASIENOMMERS/ VERWYSINGSNOMMERS:

EVISTA 60 mg (Tablette): 32/34/0423

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:

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