V1.1 (17/06/2021)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ESTRADOT® 25 (Transdermal Patch)

ESTRADOT® 37,5 (Transdermal Patch)

ESTRADOT® 50 (Transdermal Patch)

ESTRADOT® 75 (Transdermal Patch)

ESTRADOT® 100 (Transdermal Patch)

Estradiol hemihydrate

Sugar free

Please read this leaflet carefully before using ESTRADOT.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ESTRADOT 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.

1. WHAT ESTRADOT CONTAINS:

ESTRADOT transdermal patches contain estradiol hemihydrate.

Five ESTRADOT Transdermal delivery system patches are available:

	Nominal delivery µg/day	***Estradiol (as hemihydrate) mg***	***Surface area (cm^2)***
ESTRADOT 25	25	0,39	2,5
ESTRADOT 37,5	37,5	0,585	3,75
ESTRADOT 50	50	0,78	5

ESTRADOT 75	75	1,17	7,5
ESTRADOT 100	100	1,56	10

The composition of each transdermal patch per unit area is identical.

The other ingredients are: adhesive layer: (BIO-PSA silicone adhesive, dipropylene glycol, Gelva 788 acrylic adhesive, oleyl alcohol, povidone), backing layer film: (ethylene vinyl acetate and vinylidine chloride/ methyl acrylate copolymer layers) and release liner (fluoropolymer-coated polyester: (removed before use)).

2. WHAT ESTRADOT IS USED FOR:

ESTRADOT is used to relieve symptoms you may experience at the time of the menopause (the time when your menstrual periods stop), whether occurring naturally or as a result of a surgery.

It can also be used to prevent osteoporosis (thinning of the bones, which causes fractures), the risk of which may be increased after the menopause.

You and your doctor should discuss the benefits and risks of ESTRADOT and other alternative therapies.

Relief of the symptoms of the menopause:

ESTRADOT is used to help relieve the discomfort that you may experience during and after the menopause. Menopause occurs naturally in all women, usually between the ages of 45 and 55. It also occurs in younger women who have their ovaries removed by surgery. After the menopause, your body produces estrogens in much smaller amounts than it did before. This can cause unpleasant symptoms such as hot face, neck and chest, "hot flushes" (sudden waves of heat and sweating in the whole body), sleep problems, irritability and depression.

Estrogens can be given to reduce or eliminate these symptoms.

Prevention of osteoporosis:

After the age of 40, and especially after the menopause, some women develop osteoporosis. This is a thinning of the bones that makes them weaker and more likely to break. It affects the bones of the spine, hip and wrist in particular. The risk of osteoporosis is increased by a lack of estrogens. Taking estrogens after the menopause slows down bone loss and can help to prevent osteoporosis. You and your doctor should discuss the benefits and risks of ESTRADOT and other alternative therapies.

ESTRADOT should not be used to prevent heart disease.

ESTRADOT is not a contraceptive, nor will it restore fertility.

Ask your doctor if you have any questions about how ESTRADOT works or why this medicine has been prescribed for you.

3. BEFORE YOU USE ESTRADOT:

Follow all instructions given to you by your doctor or pharmacist carefully.

Read the following information before you use ESTRADOT.

Do not use ESTRADOT:

- If you have ever had any unusual or allergic reaction to estrogens or any of the other components of the patch.
- If you currently have or have ever had a cancer of the breast, endometrium (lining of the womb) or any other cancer which is sensitive to estrogens.
- If you have abnormal vaginal bleeding.
- If you currently have a severe liver disease.
- If you currently have a problem with blood clot forming in your blood vessels or have ever had such a problem in the past. This may cause a painful inflammation of the veins (thrombophlebitis) or blockade of a blood vessel in the leg (deep vein thrombosis), the lungs (pulmonary embolism), or other organs.
- If you have ever had a heart attack or stroke.
- If you have had several miscarriages.
- If you are pregnant or think you may be pregnant.
- If you are breastfeeding.
- If you have depression, which is not well controlled with treatment.

- If you have had depression with previous use of estrogen and/or progesterone/progestogen containing medicines.

Talk to your doctor if you have any further questions or if you think that any of the above may apply to you.

Further safety measures:

Before you start using ESTRADOT you will discuss with your doctor your personal medical history and that of your family. You will also be given a complete physical and gynaecological examination.

Tell your doctor if you currently have, or have ever had, any of the following conditions:

- Breast cancer in your immediate family.
- Lumps in your breast.
- Fibroids or other benign tumours of the womb.
- Endometriosis (disorder of the pelvis causing painful menstrual periods).
- Jaundice or itching related to estrogen use or during pregnancy.
- Heart, kidney, or liver problems.
- Gall bladder disease.
- High blood pressure.
- Asthma.
- Epilepsy.
- Diabetes.
- Migraine.
- Otosclerosis (hearing loss due to a problem with the bones in the ear).

Your doctor may want to take special precautions if you have any of these conditions.

Make sure you tell your doctor if you think you may be at increased risk of formation of blood clots in your blood vessels. The risk increases with age and may also be increased:

- If you or anyone in your immediate family has ever had blood clots in the blood vessels of the legs or the lungs.
- If you have systemic lupus erythematosus (a connective tissue disease).

- If you are overweight.
- If you have varicose veins.

Warnings and precautions:

Tell your doctor before using ESTRADOT:

- If you are on treatment for depression.
- If you have had depression with previous use of estrogen and/or progesterone/progestogen containing medicines.
- If you have a substance abuse problem.
- If you have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- If you have a family history of mental disorders.
- If you have a history of physical or sexual abuse.

Estrogen and/or progesterone/progestogen containing medicines including ESTRADOT, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression contact your doctor for advice.

Taking other medicines with ESTRADOT:

Always tell your doctor or healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

This particularly includes the following: anti-anxiety medicines (e.g. meprobamate), anti-epileptic medicines (e.g. phenylbarbital, phenytoin or carbamazepine), an anti-inflammatory medicine called phenylbutazone, antibiotics and other anti-infective medicines (e.g. rifampicin,

rifabutin, nevirapine, efavirenz, ritonavir, nelfinavir), and herbal medicines (e.g. St. John's wort). These medicines may be affected by ESTRADOT or, conversely, they may affect how well ESTRADOT works. Your doctor may need to adjust the dose of your treatment.

Use in children:

ESTRADOT is not to be used in children.

Pregnancy and breastfeeding:

Pregnancy:

Do not use ESTRADOT if you are pregnant. It may affect your baby if used during pregnancy.

Ask your doctor or pharmacist for advice.

ESTRADOT is not a contraceptive and does not prevent pregnancy.

If you are taking the pill, or using another hormonal contraceptive, you will need to use a different, non-hormonal contraceptive method during ESTRADOT therapy.

Please discuss this with your doctor.

Breastfeeding:

Do not breastfeed while using ESTRADOT.

Ask your doctor or pharmacist for advice.

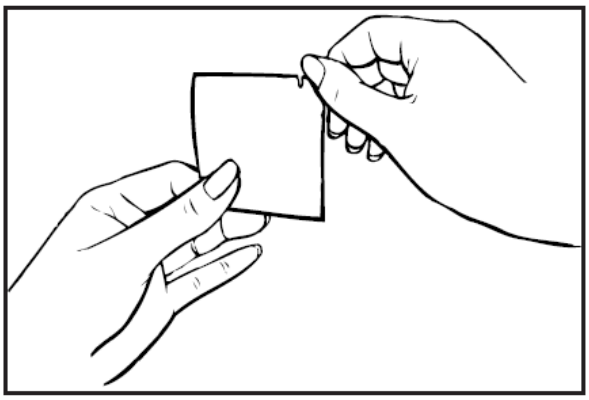
Driving and using machinery:

ESTRADOT has no known effects on the ability to drive or use machines.

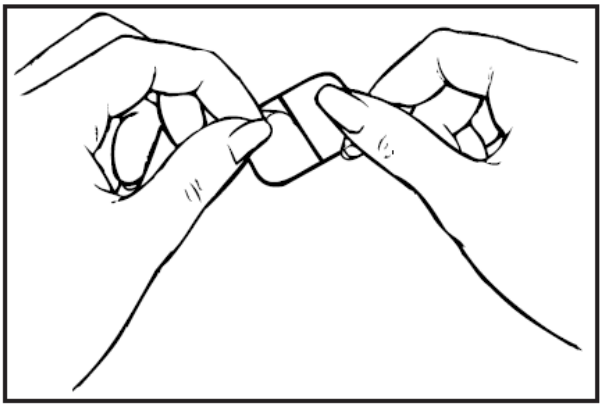
4. HOW TO USE ESTRADOT:

How to apply ESTRADOT:

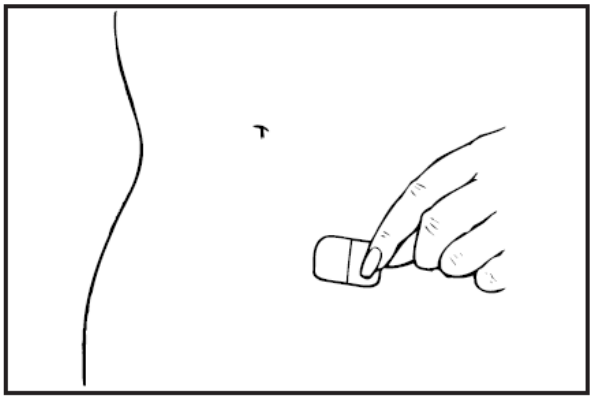
Each patch is individually sealed in a protective pouch. Tear open this pouch at the indentation and remove the patch (do not use scissors to open the pouch as this could damage the patch).



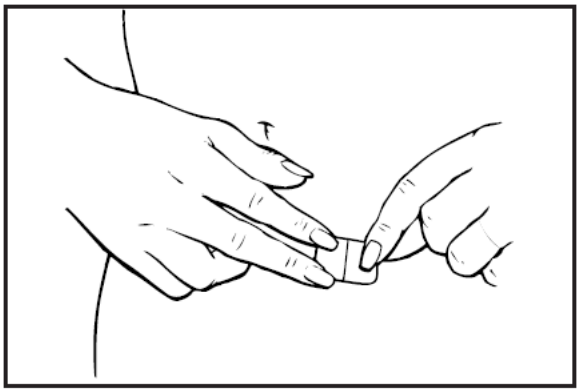
A stiff protective backing covers the sticky side of the patch. This backing must be removed before the patch is stuck to the skin. Hold the patch with the protective backing facing you.



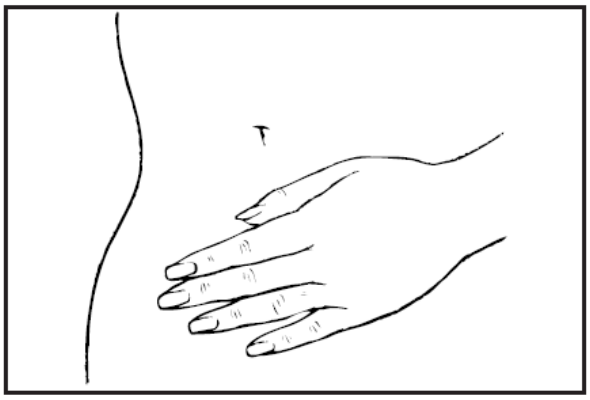
Peel off one side of the protective backing and discard it. Try to avoid touching the sticky side of the patch with your fingers.



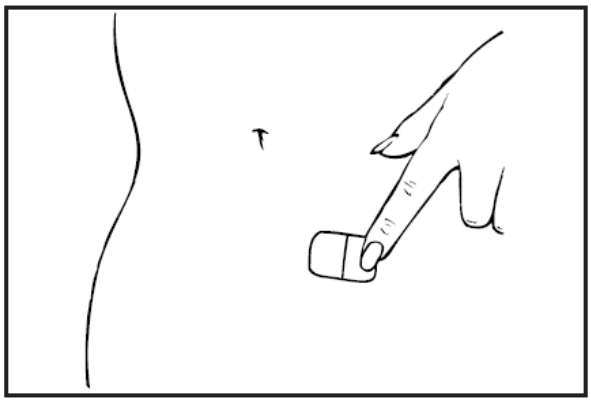
Holding the other half of the backing, apply the sticky side of the patch to a dry area of your abdomen. Press the sticky side to the skin and smooth down. Fold back the remaining side of the patch.



Grasp the straight edge of the protective backing and pull it off the patch.



Press the patch firmly in place with the palm of your hand for about 10 seconds.



Make sure that the patch is properly adhered to your skin and go over the edges with your finger to ensure good contact around the patch.
Apply the patch immediately after opening the pouch and removing the protective backing.

ESTRADOT should be worn continuously until it is time to replace it with a new patch. You may wish to experiment with different locations when applying a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch.

Other useful information:

- Bathing, swimming, showering or exercising should not affect the patch if it has been applied correctly. If the patch does come off, e.g. in the bath or shower, just shake it to remove any water, dry the skin thoroughly, reapply it and continue with your regular schedule.
- Sunbathing: always make sure your patch is covered by clothing.
- Swimming: you can wear the patch under your swimming costume.
- Never apply a patch to sweaty skin or straight after a hot bath or shower. Wait until the skin is completely cool and dry.
- If a patch falls off, the same patch may be put on a different area of your abdomen. Make sure you choose a clean, dry, lotion-free area of skin. If the patch does not stick

completely to your skin, use a new patch. No matter what day this happens, go back to changing the patch on the same days as the initial schedule.

Do not share medicines prescribed for you with others.

If you use more ESTRADOT than you should:

Because of the way it is administered, it is unlikely that you will use more ESTRADOT than you should. If this does happen, contact your doctor immediately.

If you forget to use ESTRADOT:

If you miss applying a patch, reapply another patch as soon as you remember. No matter what day that happens, go back to changing the patch on the same days as your initial schedule.

While you are using ESTRADOT:

See your doctor regularly and at least once a year for check-up. Some women will need to go more often. You should discuss with your doctor the need for adjusting or continuing therapy. Your doctor will check your breasts and your pelvis. It is important to learn how to examine your own breasts and do this regularly. This helps to prevent unwanted effects of HRT. Tell your doctor if you suspect any abnormality.

Tell your doctor well in advance of any expected hospitalisation or surgery. If you have to go into hospital unexpectedly, tell the doctor who admits you that you are using ESTRADOT. The risk of developing blood clots in your blood vessels may be temporarily increased as a result of an operation, serious injuries or having to stay in bed for a prolonged period. ESTRADOT should not be restarted until you are fully mobile.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ESTRADOT.

Ask your doctor or pharmacist to answer any questions you may have.

5. POSSIBLE SIDE EFFECTS:

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor immediately and remove the patch if any of the following occur:

- Signs of an allergic reaction: sudden troubled breathing, tightness of the chest, general rash, swelling or itching.
- Signs of jaundice: yellowing of the eyes or the skin.
- Signs that blood clots may have formed in your body: pains in the calves, thighs or chest, sudden shortness of breath, coughing blood or dizziness.
- Signs of heart attack: chest pain, dizziness, nausea, shortness of breath, irregular pulse.
- Signs of stroke: collapse, numbness or weakness of the arms and the legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech.

The above side effects are serious and require urgent medical attention. Most of these side effects are rare.

Tell your doctor if you notice any of the following:

- Depression, headache, migraine, dizziness, uncontrollable jerky movements (chorea).
- Nausea, vomiting, cramps in the abdomen, bloated feeling.
- Spotty darkening of the skin, particularly on the face (chloasma).
- Redness, rash, or itching of the skin after the patch has been removed, hair loss, excessive hairiness.
- Vaginal bleeding or spotting.
- Enlargement in size of fibroids.
- Vaginal thrush (vaginal fungal infection with severe itching, vaginal discharge).
- Changes in vaginal discharge.
- Tender or enlarged breasts.
- Change in weight.
- Swelling of the lower legs, ankles, fingers or abdomen due to fluid retention (oedema).
- Changes in your sex drive.
- Contact lens discomfort.

- Worsening of porphyria (a condition affecting the liver).
- Gall bladder disease (tendency to form gall stones).

The following side effect is reported from post-marketing experience:

- Suicidal thoughts/behavior and suicide.

If you notice any side effects not mentioned in this leaflet, tell your doctor.

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF ESTRADOT:

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.
- Store ESTRADOT in the original package in a cool, dry place. Once opened or once the protective pouch has been removed, the patch should be applied to the skin immediately.
- Do not refrigerate or freeze ESTRADOT.
- Do not use ESTRADOT after the expiry date shown on the box.
- Do not use any ESTRADOT pack that is damaged or shows signs of tampering.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ESTRADOT:

Each ESTRADOT transdermal patch is individually sealed in a Coex aluminium foil laminate heat-sealed sachet made of paper/LDPE/aluminium/ethylene methacrylic acid copolymer-LDPE.

Sachets may be provided in cartons of 8 or 24.

Not all packs sizes may be marketed.

8. IDENTIFICATION OF ESTRADOT:

A rounded rectangle transdermal patch. Pressure-sensitive adhesive with a translucent polymeric backing on one side and a release liner on the other. The patch is contained in a heat-sealed pouch (paper/polyethylene/foil/polyethylene).

9. REGISTRATION NUMBERS:

ESTRADOT 25:	37/21.8.1/0493
ESTRADOT 37,5:	37/21.8.1/0215
ESTRADOT 50:	37/21.8.1/0216
ESTRADOT 75:	37/21.8.1/0217
ESTRADOT 100:	37/21.8.1/0218

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

DATE OF PUBLICATION:

Date of registration:

ESTRADOT 25:	28 May 2004
ESTRADOT 37,5:	05 September 2003
ESTRADOT 50:	05 September 2003
ESTRADOT 75:	05 September 2003
ESTRADOT 100:	24 October 2003

Date of most recent approval of patient information leaflet: 06 September 2021

[1]Company Reg. No.: 1990/001979/07