Estradot Conti 30/95 transdermal patch, 30 micrograms/24 hours and 95 micrograms/24 hours
Estradot Conti 40/130 transdermal patch, 40 micrograms/24 hours and 130 micrograms/24 hours

estradiol/norethisterone acetate

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 Estradot Conti is and what it is used for
2. What you need to know before you take Estradot Conti
3. How to take Estradot Conti
4. Possible side effects
5. How to store Estradot Conti
6. Contents of the pack and other information

SANDOZ

1 What Estradot Conti is and what it is used for

Estradot Conti is a Hormone Replacement Therapy (HRT). It contains two types of female hormones, an oestrogen and a progestogen. Estradot Conti is used in postmenopausal women with at least 1 year since their last natural period.

Estradot Conti is used for:

Relief of symptoms occurring after menopause
During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Estradot Conti alleviates these symptoms after menopause. You will only be prescribed Estradot Conti if your symptoms seriously hinder your daily life.

There is only limited experience of treating women older than 65 years with Estradot Conti.

2 What you need to know before you take Estradot Conti

Medical history and regular check-ups
The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on Estradot Conti you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Estradot Conti.

Go for regular breast screening, as recommended by your doctor.

Do not use Estradot Conti if any of the following applies to you. If you are not sure about any of the points below, talk to your doctor before using Estradot Conti.
Do not use Estradot Conti:
- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you **have cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any **unexplained vaginal bleeding**
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited)
- If you are **allergic** to estradiol or norethisterone acetate, soya, peanut or any of the other ingredients of this medicine (listed in section 6)

If any of the above conditions appear for the first time while using Estradot Conti, **stop using it at once and consult your doctor immediately.**

Warning and precautions
Talk to your doctor or pharmacist before using Estradot Conti. Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Estradot Conti. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- increased risk of getting a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- a condition called hypothyroidism (your thyroid gland fails to produce enough thyroid hormone) and you are taking a thyroid hormone replacement therapy;
- a condition called hereditary and acquired angioedema or if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract.

Stop using Estradot Conti and see a doctor immediately

If you notice any of the following when taking HRT:

- any of the conditions mentioned in the 'DO NOT use Estradot Conti' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness).
- migraine-like headaches which happen for the first time.
- if you become pregnant
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs
  - sudden chest pain
  - difficulty in breathing

For more information, see 'Blood clots in a vein (thrombosis)'

Note: Estradot Conti is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

The progestogen in Estradot Conti protects you from this extra risk.

Irregular bleeding
You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of using Estradot Conti. However, if the irregular bleeding:
- carries on for more than the first 6 months
- starts after you have been using Estradot Conti for more than 6 months
- carries on after you have stopped using Estradot Conti

see your doctor as soon as possible

Breast cancer
Evidence shows that taking combined oestrogen-progestogen or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare
Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period.
For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases).
For women aged 50 who start taking oestrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period.
For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases)
For women aged 50 who start taking oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

Regularly check your breasts. See your doctor if you notice any changes such as:
- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/ healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer
Ovarian cancer is rare – much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer. The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)
The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:
- you are unable to walk for a long time because of major surgery, injury or illness (see also Section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m^2)
- pregnancy/ postpartum period
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see "Stop using Estradot Conti and see a doctor immediately".

Compare
Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

Heart disease (heart attack)
There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke
The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Compare
Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions
HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

All medicines used on the skin (like patches) may cause allergic skin reactions. Although it occurs very rarely, you should tell your doctor if you have, or have ever had, a severe allergic reaction to any of the ingredients of the patch.

Other medicines and Estradot Conti
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
Some medicines may interfere with the effect of Estradot Conti. This might lead to irregular bleeding. This applies to the following medicines:
- Medicines for epilepsy (such as phenobarbital, phenytoin and carbamazepin)
- Medicines for tuberculosis (such as rifampicin, rifabutin)
- Medicines for HIV infection (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Medicines for **Hepatitis C infections** (such as telaprevir)
- Other anti-infective medicines (such as ketoconazole, erythromycin).
- Herbal remedies containing St John's Wort (Hypericum perforatum).

HRT can affect the way some other medicines work:
- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures

Continued on the next page>>

- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Estradot Conti contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Estradot Conti with this HCV combination regimen. Your doctor will advise you.

Estradot Conti may affect the metabolism of cyclosporine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are using Estradot Conti, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding
Estradot Conti is for use in postmenopausal women only. If you become pregnant, stop using Estradot Conti and contact your doctor.
Do not use Estradot Conti while you are breast-feeding.

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
No known adverse effect of Estradot Conti on the ability to drive and use machines have been reported.

Estradot Conti contains soya oil.
If you are allergic to peanut or soya, do not use this medicine.

3 How to use Estradot Conti

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

Estradot Conti should be applied twice a week, i.e. a new transdermal patch should be applied every 3 or 4 days.

Apply the Estradot Conti patches continuously (without interruption).

	week 1		week 2		week 3		week 4	
Apply the Estradot Conti transdermal patch	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4

When to start treatment
- In women who have never used hormone replacement therapy before or women who change from continuous combined hormone replacement therapy, the treatment can be started on any day.
- In women who are changing form a cyclic or continuous sequential hormone replacement therapy, the treatment should start on the day immediately following completion of the preceding cycle.

Method of use
Where to apply the patch
- You should stick the patch on an area of the skin where little wrinkling of skin occurs during movement, such as on the side of the upper thigh. Do NOT apply these patches to the breast!
- The skin should not be red or injured
- The site where you stick the patch should be hair free
- Avoid areas of the skin where clothing may pinch or under clothing edges
- Clean the skin thoroughly before you stick the patch on the skin. Do not use body-lotion, body oil, shower gel, suntan products or other products containing a fatty substance. The skin must be dry and not oily.

Open the pack
- Tear the pack open carefully by one of the two corners, along the perforation, just before use
- Hold the patch by the edge and remove it from the pack.

Note: the drying agent attached to the inner side of the pack is intended to ensure the quality of the product, and must not be used on the skin.

Remove the protective film
- Hold the protective liner with both hands
- Carefully bend the patch up and down along the perforated curved line
- Carefully peel off most of the transparent protective liner from the patch
- Do not touch the adhesive layer of the patch.

Sticking the patch on
- Stick the adhesive part of the patch evenly on the body, make sure there are no air bubbles under it
- Remove the remainder of the protective liner and stick the remaining part of the patch to the skin
- Press the patch for one minute with the flat of your hand; the Estradiol patch is now applied correctly.

Using the patch
- You can take a bath of shower while wearing the patch. The patch may come off in very hot bathwater or in a sauna.
- Avoid the use of fatty crèmes, lotions and powders on the application site of the patch
- The patch may become less active if exposed to sunlight or artificial sunlight (e.g. in a solarium).

Applied correctly, Estradot Conti adheres well and normally sticks on for at least 4 days without any problem.
If the patch has not been applied correctly or has come off during use, it should not be reused. You should use a new patch. The patch should be changed on the usual day. Forgetting to apply a patch may increase the risk of a breakthrough bleeding or spotting.

New patch
- After use the patch should be taken off, folded up with the sticky side inwards and thrown away.
- Apply a new patch to another area of the skin.

Duration of treatment
Your doctor has told you how long you should continue the treatment. It is important that you should keep to these instructions. If you wish to stop the treatment sooner, please consult your doctor. Together with your doctor you should have a periodic reassessment of your need for oestrogen treatment. This should be done at least once a year.

Pediatric population
Estradiol/norethisterone is not indicated for use in children.

If you use more Estradot Conti than you should
If more transdermal patches have been applied than the prescribed number of patches or if an overdose is suspected, you should remove the patch(es) and consult a doctor or pharmacist immediately. Symptoms of overdose can be: tender breasts, metrorrhagia, nausea, vomiting, painful or bloated feeling in the abdomen, anxiety, irritability, and fluid retention. Flatulence, depressive mood, fatigue, acne and hirsutism may also occur as a symptom of overdose. These symptoms disappear when you remove the patch.

If you forget to use Estradot Conti
Please apply a new transdermal patch as soon as possible, unless it is almost time to apply the next one according to your usual schedule. In that case you should wait and just keep to your usual schedule. Never apply two patches simultaneously. Forgetting to apply a patch may increase the risk of breakthrough bleeding.

If you need to have surgery
If you are going to have surgery, tell the surgeon that you are using Estradot Conti. You may need to stop using Estradot Conti about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start using Estradot Conti again.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:
- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see Section 2.

Hypersensitivity/allergy may occur. Signs of hypersensitivity/allergy may include one or more of the following symptoms: hives, itching, swelling, difficulty in breathing, low blood pressure (paleness and coldness of skin, rapid heartbeat), feeling dizzy, sweating, which could be signs of anaphylactic reaction/shock. If one of the mentioned symptoms appears, **stop taking Estradot Conti and seek immediate medical help.**

Other serious side effects:
- benign tumor of the womb, cysts around the tube, polyps in the cervix
- cholestatic jaundice

Other serious side effects, disorders and risks associated with HRT are listed in section 2 under “Warnings and precautions”.

The following side effects have been reported with the use of Estradiol/Norethisteron acetate:

Very common: may affect more than 1 in 10 people
- headache
- skin reactions at the site of application
- breast tension and pain, painful menstruation (dysmenorrhea), menstrual disorder

Common: may affect up to 1 in 10 people
- depression, nervousness, uncontrollable emotions, mood changes
- dizziness, insomnia
- nausea, abdominal distension, diarrhea, gastric disorders (dyspepsia), flatulence, abdominal pain
- acne, rash, pruritus, dry skin, redness of the skin (erythema)
- back pain, pain in hands or feet
- breast enlargement, heavy periods, genital discharge, irregular vaginal bleeding, uterine spasms, infection of the vagina, abnormal growth of the lining of the womb
- pain, lack or loss of strength (asthenia), swollen hands, ankles or feet (oedema), weight gain

Uncommon: may affect up to 1 in 100 people
- migraine, spinning sensation
- rise in blood pressure, varicose veins
- vomiting
- skin discoloration
- increase in special liver enzymes (transaminases)

Rare: may affect up to 1 in 1,000 people
- allergic reactions
- changes in sexual desire (altered libido)
- sensations of tickling, itching or tingling without an apparent cause
- gallbladder disorders, gallstones
- muscle weakness (myasthenia)

Not known: frequency cannot be estimated from the available data
- hair loss

Other possible side effects:
- partially hydrogenated soya oil may very rarely cause allergic reactions

The following side effects have been reported with other HRTs:

- gallbladder disease
- various skin disorders
  - discoloration of the skin especially of the face or neck known as “pregnancy patches” (chloasma)
  - painful reddish skin nodules (erythema nodosum)
  - rash with target-shaped reddening or sores (erythema multiforme)
  - pinpoint bleeding spots in the skin (vascular purpura)
- dementia over the age of 65
- dry eyes
- tear film composition changes

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Estradot Conti

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the sachet and on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original package.

Disposal of used and unused patches: Dispose of used patches with care. After use the patch still contains considerable quantities of ingredients. Remaining hormonal active ingredients of the patch may have harmful effects if reaching the aquatic environment. Therefore be sure to fold the used patch in half, adhesive side inwards, so that the sticky side is not exposed. Any used or unused patches should be discarded away from the sight and reach of children and according to local requirements or returned to pharmacy. To help protect the environment, do not flush used patches down the toilet or place in liquid disposal systems.

6 Contents of the pack and other information

What Estradot Conti contains

The active substances are estradiol and norethisterone acetate.

Each patch contains 3.2 mg estradiol (as estradiol hemihydrate) and 16 mg norethisterone acetate per 20 cm^2 (matrix system). It releases an average of 30 micrograms estradiol and 95 micrograms norethisterone acetate per day (24 h).

Each patch contains 4.32 mg estradiol (as estradiol hemihydrate) and 21.6 mg norethisterone acetate per 27 cm^2 (matrix system). It releases an average of 40 micrograms estradiol and 130 micrograms norethisterone acetate per day (24 h).

The other ingredients are:
Protective liner: Polyester foil, siliconized
Matrix layer: Vitamin E preparation (contains: d-α-tocopherol concentrate, partially hydrogenated vegetable oil (mainly soybean oil)), acrylic copolymer
Backing foil: Polyester foil, not siliconized

What Estradot Conti looks like and contents of the pack

Estradot Conti are angular, transparent transdermal matrix patches with rounded corners located on an oversized removable protective liner.

Original packages containing 8, 16, and 24 transdermal patches, each individually hot sealed in a protective pack.

Each pack is composed from outside to inside of the following four layers: paper, polyethylene foil, aluminium foil, polyethylene foil and an attached polypropylene layer with moisture- and oxygen-absorbing properties.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

Manufacturer:
Hexal AG
Industriestrasse 25
83607 Holzkirchen, Germany

This leaflet was last revised in 02/2025