PROFESSIONAL INFORMATION

SCHEDULING STATUS
Schedule 4

PROPRIETARY NAME AND DOSAGE FORM
EVOREL® CONTI
Patch

COMPOSITION
Each EVOREL CONTI contains 3,1 mg oestradiol, formulated as 3,2 mg of oestradiol hemihydrate and 9,82 mg norethisterone, formulated as 11,2 mg of norethisterone acetate. The patch delivers 50 µg of oestradiol and 170 µg of norethisterone acetate per 24 hours.

EVOREL® CONTI is a matrix type transdermal patch.

The following are the inactive ingredients of EVOREL CONTI:
Adhesive: acrylate vinylacetate copolymer
Guar gum
Backing film: polyethylene terephthalate foil
Release liner: silicinised polyethylene terephthalate foil which is removed before application.
EVOREL® CONTI contains no sugar.

PHARMACOLOGICAL CLASSIFICATION
A 21.8.2 Progesterones with oestrogens

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
EVOREL CONTI contains oestradiol hemihydrates (17β – oestradiol), which is a synthetically prepared oestrogen and norethisterone acetate, the acetate ester or norethisterone, a synthetic progestin.

Oestradiol (E_2)
After application to the skin the patch delivers
17ß- oestradiol, a physiological hormone, transdermally into the systemic circulation and consequently, the 17ß-oestradiol does not undergo first pass liver metabolism.
In postmenopausal women, EVOREL CONTI raise the oestradiol concentrations to levels similar to those in the early follicular phase and maintain these levels over the application period of 3 – 4 days.
The oestradiol/oestrone ratio in the plasma of post-menopausal women is between 0,2 to 0,5 which increases after the transdermal application of oestradiol to approximately 1 (normal pre menopausal levels; early follicular phase).

Norethisterone acetate (NETA)
Norethisterone acetate, used in the EVOREL CONTI, is hydrolysed to norethisterone, a synthetic 19-nortestosterone derivative of the 13-methyl gonane group with potent progestational activity.
Transdermal norethisterone acetate administration prevents oestrogen related endometrial proliferation.

Pharmacokinetic Properties
Oestradiol
Oestradiol distributes widely in the body tissues and is bound to albumin (about 60 – 65 %) and sex-hormone-binding globulin (about 35 – 45 %) in serum. Serum protein binding fractions remain unaltered following transdermal delivery of oestradiol. Oestradiol is promptly eliminated from the systemic circulation.
Oestradiol is metabolised principally into the less pharmacologically active oestrone and its conjugates.
Oestradiol, oestrone and oestrone sulphate are interconverted to each other and are excreted in urine as glucuronides and sulphates. The skin metabolises oestradiol only to a small extent.

Norethisterone
Norethisterone acetate is hydrolysed to the active progestogen, norethisterone. Transdermal delivery of norethisterone acetate produces a sustained level of norethisterone in the systemic circulation.
Norethisterone distributes widely in the body tissues and is bound to albumin (about 61 %) and sex hormone binding globulin (about 36 %) in serum.
Norethisterone is primarily metabolised by the liver by reduction of the α, ß unsaturated ketone structure in ring A of the molecule.
Among the four possible stereoisomeric tetrahydrosteroids, the 5ß-, 3α-hydroxy-derivative appears to be the predominant metabolite.
These compounds are primarily excreted in urine and faeces as sulphates and glucuronide conjugates.

E_2/NETA combination
Oestradiol: In a single and multiple application study in post menopausal women, serum oestradiol concentrations increased rapidly from pre treatment levels (about 5 pg/ml) after application of an EVOREL CONTI.
At four hours after application, the mean serum oestradiol concentration was about 19 pg/ml. A mean peak serum oestradiol concentration of about 41 pg/ml above the pre treatment level was observed at about 23 hours following application.
Serum oestradiol concentrations remained elevated for the 3,5 day application period. Concentrations returned rapidly to pretreatment levels within 24 hours following removal of the patch.
A serum half-life of about 6,6 hours was determined following removal of the patch. Multiple application of the patch resulted in little or no accumulation of oestradiol in the systemic circulation.

During use of EVOREL CONTI, the E_2/E_1 ratios increased rapidly and were maintained at physiological levels at approximated 1. The E_2/E_1 ratios returned to pretreatment levels within 24 hours after removal of the patch.

Norethisterone: In a single and multiple application study in postmenopausal women, serum norethisterone concentrations rose within 1 day after application of an EVOREL CONTI to a mean steady state level of about 199 pg/ml.
Mean steady state serum norethisterone concentrations ranging between about 141 – 224 pg/ml were maintained for the entire 3,5 day application period following multiple applications. Mean concentrations declined rapidly to the lower limit of assay quantitation at 24 hours after removal of the patch.

A serum half life of about 15 hours was determined following removal of the patch, indicative of the skin depot effect. As expected from the transdermal delivery only a transient and limited increase in serum norethisterone concentrations was observed following multiple application of the patch.

INDICATIONS
Hormone replacement therapy (HRT) for the relief of menopausal symptoms (vasomotor symptoms such as hot flushes and atrophic vaginitis/vulvitis for women with an intact uterus).

CONTRAINDICATIONS
- Known hypersensitivity to oestradiol, norethisterone acetate or any other component of this product.
- Known current or past or suspected breast cancer.
- Family history of breast cancer.
- Known or suspected oestrogen dependent malignant tumours (e.g. endometrial cancer) or pre-malignant tumours (e.g. untreated atypical endometrial hyperplasia).
- Undiagnosed genital bleeding.
- Pregnancy and lactation. (see PREGNANCY AND LACTATION)
- Active liver disease or a history of liver disease as long as liver function tests have failed to return to normal.
- Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism).
- Known thrombophilic conditions.
- Inherited thrombophilia.
- Active or past arterial thromboembolic disease (e.g. cerebrovascular accident, myocardial infarction).
- Porphyria.
- Patients known with inherited genetic mutations: BRCA 1 and BRCA 2 genes.
- Early menstrual periods (before age 12 years).
- History of non-cancerous breast diseases (atypical hyperplasia or lobular carcinoma in situ).
- Previous treatment using radiation therapy to the chest or breast.
- Previous treatment with diethylstilboestrol (DES).
- Depression not well controlled with treatment.
- A history of depression with the use of oestrogen and/or progesterone/ progestogen containing medicines irrespective of the indication, dosage formulation and route of administration.

WARNINGS AND SPECIAL PRECAUTIONS
Prior to commencing, and periodically during therapy, it is recommended that the patient be given a thorough physical and gynaecological examination. A complete medical and family history of thrombophlebitis or thromboembolic disorders should be taken.
Repeated breakthrough bleeding, unexplained vaginal bleeding, and changes noticed during breast examination require further evaluation.
A careful appraisal of the risk/benefit ratio should be undertaken before the initiation of treatment.

Conditions which need supervision:
If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, the patient should be closely supervised. It should be taken into account that these conditions may recur or be aggravated during treatment with EVOREL CONTI, in particular:
- Leiomyoma (uterine fibroids) or endometriosis
- Risk factors for thromboembolic disorders (see below)
- Risk factors for oestrogen dependent tumours, e.g. first degree relative with breast cancer
- Hypertension
- Liver disorders
- Diabetes mellitus
- Cholelithiasis
- Migraine or severe headache
- Systemic lupus erythematosus
- A history of endometrial hyperplasia (see below)
- Epilepsy
- Mastopathy.

Conditions which require monitoring while on EVOREL CONTI therapy:
- Oestrogens such as in EVOREL CONTI may cause fluid retention. Cardiac or renal dysfunction should be carefully observed
- Disturbances of liver function
- History of cholestatic jaundice
- Pre existing hypertriglyceridaemia. Cases of large increases of plasma triglycerides leading to pancreatitis have been reported in this condition.

Reasons for immediate withdrawal of therapy:
Therapy should be discontinued in case a contraindication is discovered and in the following situations:
- Jaundice or deterioration in liver function
- Increase in blood pressure
- New onset of migraine-type headache
- Pregnancy.

Breast cancer:
EVOREL CONTI contains oestrogen only which, on prolonged use, may increase the risk of developing breast cancer. A meta-analysis of prospective epidemiological studies from 1992 to 2018 reported a significant increase in the risk of developing breast cancer in 55 575 women 40 – 59 years of age who used menopausal hormone therapy (MHT).
The risk increased steadily with duration of use and was slightly greater for oestrogen-progestogen than oestrogen only preparations, and the risk persisted for more than 10 years after stopping the treatment.
The relative risk (RR) to develop breast cancer for oestrogen-progestogen preparations was 1,60 at 1 – 4 years and RR = 2,08 at 5 – 14 years, while that for oestrogen only preparations was 1,17 at 1 – 4 years and 1,33 at 5 – 14 years. There was no risk to develop breast cancer in women who started MHT at 60 years of age. All women on EVOREL CONTI should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. Mammography evaluations should be done on patient age, risk factors and prior mammogram results.

Combined oestrogen progestogen therapy:
The randomised placebo-controlled trial the Women's Health Initiative study (WHI), and epidemiological studies are consistent in finding an increased risk of breast cancer in women taking combined oestrogen progestogen for HRT that becomes apparent after about 3 years.

Oestrogen-only therapy:
The WHI trial found no increase in the risk of breast cancer in hysterectomised women using oestrogen-only HRT. The excess risk becomes apparent within a few years of use but returns to baseline within a few (at most five) years after stopping treatment. HRT, especially oestrogen progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer.

Ovarian Cancer:
Long term (at least 5 years) use of oestrogen only HRT products in hysterectomised women has been associated with an increased risk of ovarian cancer in some epidemiological studies.
Some studies including the WHI trial suggest that the long-term use of combined HRTs such as in EVOREL CONTI may also confer an increased risk.

Venous thromboembolism:
Hormone replacement therapy (HRT) is associated with a higher relative risk of developing venous thromboembolism (VTE), such as deep vein thrombosis or pulmonary embolism. One randomised controlled trial and epidemiological studies found a two-to threefold higher risk for users compared with non-users.
Personal or a strong family history of recurrent thromboembolism or recurrent spontaneous abortions should be investigated in order to exclude a thrombophilic predisposition. Until a thorough evaluation of thrombophilic factors has been made or anticoagulant treatment is initiated, the use of EVOREL CONTI in such patients should be viewed as contraindicated.
Those women already on anticoagulant treatment require careful consideration of the benefit/risk of use of EVOREL CONTI.
The risk of VTE may be temporarily increased with prolonged immobilisation, major trauma surgery. Scrupulous attention should be given to prophylactic measures to prevent VTE following surgery. Where prolonged immobilisation is liable to follow elective surgery EVOREL CONTI treatment should be discontinued four to six weeks, and earlier if possible ahead of surgery. Treatment should not be restarted until after the woman is completely mobilised.

If VTE develops after initiating therapy, EVOREL CONTI should be discontinued. Patients should be told to contact their doctors immediately when they become aware of a potential thromboembolic symptom (e.g., painful swelling of a leg, sudden pain in the chest, dyspnoea).

Coronary artery disease (CAD):
Oestrogen only:
Randomised controlled studies found no protective effect for the risk of CAD in hysterectomised women using oestrogen only therapy for the risk of CAD.

Combined oestrogen progestogen therapy such as EVOREL CONTI:
The relative risk of CAD during use of combined oestrogen progestogen HRT is increased.

Stroke:
There is an increased risk of stroke in healthy women during treatment with HRT. Combined oestrogen progestogen and oestrogen only therapy are associated with an increased risk of ischaemic stroke.

Dementia:
HRT use does not improve cognitive function. There is evidence of increased risk of dementia in women using continuous combined HRT such as EVOREL CONTI or oestrogen-only HRT.

Depressed mood, depression and the risk of suicidality:
Mood changes and depression are side effects reported with the use of hormonal containing products including EVOREL CONTI. There is some evidence that use of oestrogen and/or progesterone/progestogen containing medicines may be associated with severe depression and a higher risk of suicidal thoughts/behavior (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. Prescribers should inform their patients to contact their doctor for advice if they experience mood changes and depression whilst on treatment with EVOREL CONTI.

EVOREL CONTI is not to be used as contraception.

The EVOREL CONTI should be kept away from children.

INTERACTIONS
Medicines which induce microsomal liver enzyme activity may alter oestrogen and progestogen metabolism and reduce the therapeutic effect of EVOREL CONTI. Examples of such medicines are barbiturates, hydantoins, carbamazepine, meprobamate, phenylbutazone, rifampicin, rifabutin, bosentan and certain non nucleoside reverse transcriptase inhibitors (e.g. nevirapine and efavirenz) used in the treatment of HIV/AIDS infections.
Ritonavir and nelfinavir, although known as strong inhibitors of the cytochrome P450 isoenzymes, by contrast exhibit inducing properties when used concomitantly with steroid hormones. Metabolism may be affected by St. John's wort preparations (*Hypericum perforatum*), which induce certain cytochrome P450 isoenzymes in the liver (e.g. CYP 3A4) as well as P glycoprotein.
The induction of the P450 isoenzymes may reduce plasma concentrations of the oestrogen component of EVOREL CONTI possibly resulting in a decrease in therapeutic effects and increased vaginal bleeding.
The induction of these same isoenzymes may also reduce circulating concentrations of the progestin component of EVOREL CONTI, which could result in a diminished protective effect against oestrogen induced endometrial hyperplasia. Oestrogen-containing oral contraceptives have been shown to significantly decrease plasma concentrations of lamotrigine when co administered due to induction of lamotrigine glucuronidation.
This may reduce seizure control. Although the potential interaction between EVOREL CONTI therapy and lamotrigine has not been studied, it is expected that a similar interaction exists, which may lead to a reduction in seizure control among women taking both medicines together. Therefore, dosage adjustment of lamotrigine may be necessary.

PREGNANCY AND LACTATION
The use of EVOREL CONTI is contraindicated in pregnancy and lactation.

If pregnancy occurs during medication with EVOREL CONTI, treatment should be withdrawn immediately.

DOSAGE AND DIRECTIONS FOR USE
Dosage
ADULTS: EVOREL CONTI should be applied twice weekly, without interruption to the trunk below the waist.

Insufficient data are available to guide dose adjustments for patients with severe liver or kidney function impairment.

EVOREL CONTI should not be continued for longer than 5 years.
Should a patch fall off, it should be replaced immediately with a new patch. However, the usual day of changing patches should be maintained.
ELDERLY: Data are insufficient in regard to the use of EVOREL CONTI in the elderly (> 65 years old).

Directions for use/handling
The EVOREL CONTI should be placed on a clean, dry, healthy, intact area of skin, on the trunk of the body below the waist. Creams, lotions or powders may interfere with the adhesive properties of the patch.
The patch should not be applied on or near the breasts.
The area of application should be changed, with an interval of at least one week allowed between applications to a particular site.
The skin area selected should not be damaged or irritated.
The waistline should not be used because excessive rubbing of the patch may occur.
The patch should be used immediately after opening the sachet. Remove one part of the protecting foil. Apply the exposed part of adhesive to the application site from the edge to the middle; avoid wrinkling of the patch.
The second part of the protective foil should now be removed and the freshly exposed adhesive applied. Wrinkling should again be avoided and the palm of the hand used to press the patch onto the skin and to bring the patch to skin temperature at which the adhesive effect is optimised.
The patient should avoid contact between fingers and the adhesive part of the patch during application.
Should a patch fall off, a new patch should be applied immediately. However, the usual day of changing patches should be maintained.
It is not necessary to remove the patch during bathing or showering. It is recommended, however, that the patch be removed prior to a sauna bath, and that a new patch is applied immediately thereafter.
If a patch change is missed, the missed patch should be applied as soon as remembered. However, the usual day of changing patches should be maintained. Forgetting a dose may increase the likelihood of break through bleeding and spotting.
To remove the EVOREL CONTI patch, peel away an edge of the patch and pull smoothly away from the skin. The patches should be disposed of in household waste (do not flush down the toilet).
Any adhesive that remains on the skin after removal of EVOREL CONTI patch may be removed washing with soap and water or by rubbing it off with the fingers.

SIDE EFFECTS
Clinical Trial Data
The safety of EVOREL CONTI was evaluated in 196 subjects in 3 clinical trials (including 2 active-controlled trials and 1 single arm trial). Adverse drug reactions (ADRs) reported for ≥ 1 % of EVOREL CONTI treated subjects are shown in Table 1.

Table 1. Adverse Drug Reactions Reported by ≥ 1 % of EVOREL CONTI-treated Subjects in 3 Clinical Trials of EVOREL CONTI

System/Organ Class	*EVOREL CONTI % (N=196)*
Immune System Disorders	
Hypersensitivity	*1,0*
Psychiatric Disorders	
Depression	*2,6*
Nervousness	*2,6*
Anxiety	*1,0*
Insomnia	*1,0*
Nervous System Disorders	
Headache	*8,2*
Paraesthesia	*1,0*
Cardiac Disorders	
Palpitations	*2,6*
Vascular Disorders	
Hypertension	*3,6*
Vasodilation	*2,6*
Varicose vein	*1,0*
Gastrointestinal Disorders	
Abdominal pain	*4,1*
Nausea	*2,6*
Skin and Subcutaneous Tissue Disorders	
Rash erythematous	*1,0*
Musculoskeletal and Connective Tissue Disorders	
Arthralgia	*3,1*
Back pain	*2,6*
Reproductive System and Breast Disorders	
Menstrual disorder	*7,1*
Breast pain	*5,1*
Metrorrhagia	*3,6*
Genital discharge	*1,5*
Cervical polyp	*1,0*
Dysmenorrhoea	*1,0*
Endometrial hyperplasia	*1,0*
Menorrhagia	*1,0*
General Disorders and Administration Site Conditions	
Application site reaction	*11,7*
Oedema	*4,1*
Fatigue	*3,1*
Pain	*1,0*
Investigations	
Increased weight	*2,0*

ADRs reported by < 1 % of treated subjects (N=196) in the above clinical trial dataset are shown in Table 2.

Table 2. Adverse Drug Reactions Reported by < 1 % of treated Subjects in 3 Clinical Trials with an oestradiol and norethisterone patch

System/Organ Class	*Adverse Reaction*
Psychiatric Disorders	*Decreased libido*
Skin and Subcutaneous Tissue Disorders	*Pruritus*
General Disorders and Administration Site Conditions	*Generalised oedema*

Additional ADRs reported in clinical trials with an oestradiol patch alone in postmenopausal women are shown in Table 3.

Table 3. Adverse Drug Reactions Reported by EVOREL treated Subjects in 15 Clinical Trials (N = 2 584) of EVOREL

System/Organ Class	*Adverse Reaction*
Infections and Infestations	*Genital candidiasis*
Neoplasms Benign, Malignant and Unspecified (Incl. Cysts and Polyps)	*Breast cancer*
Nervous System Disorders	*Dizziness, epilepsy*
Vascular Disorders	*Venous & Arterial Thrombosis & embolism*
Gastrointestinal Disorders	*Diarrhoea, flatulence*
Skin and Subcutaneous Tissue Disorders	*Rash*
Musculoskeletal and Connective Tissue Disorders	*Myalgia*
General Disorders and Administration Site Conditions	*Application site rash,* Application site pruritus,* Application site erythema,* Application site oedema,* Peripheral oedema, Pain*

* Solicited signs/symptoms (recorded as yes/no) in 8 clinical trials of EVOREL (N = 1 739).

Post marketing Data
Table 4. Adverse Drug Reactions Identified During Post Marketing Experience with EVOREL CONTI

Infections and Infestations	*Candidiasis*
Neoplasms Benign, Malignant and Unspecified (Incl. Cysts and Polyps)	*Breast neoplasms, endometrial cancer*
Psychiatric Disorders	*Mood swings Severe depression with a higher risk of suicidal thoughts/behavior and suicide*
Nervous System Disorders	*Cerebrovascular accident, dizziness, migraine*
Vascular Disorders	*Deep vein thrombosis*
Respiratory, Thoracic and Mediastinal Disorders	*Pulmonary embolism*
Gastrointestinal Disorders	*Abdominal distension*
Hepatobiliary Disorders	*Cholelithiasis*
Skin and Subcutaneous Tissue Disorders	*Stevens-Johnson Syndrome*
Reproductive System and Breast Disorders	*Breast enlargement*
General Disorders and Administration Site Conditions	*Application site erythema, Application site pruritus, Application site rash*

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS
Symptoms of overdose of EVOREL CONTI therapy may include nausea, break-through bleeding, breast tenderness, abdominal cramps and/or bloating. These symptoms can be reversed by removing the EVOREL CONTI.

IDENTIFICATION
EVOREL CONTI is a flexible, square, colourless adhesive patch of 16 cm^2 with convex edges and rounded corners. The adhesive surface of the patch is covered with a protective foil with an S shaped incision.
Each patch is marked in the centre of the lower margin on the outside of the backing film: CEN1.

PRESENTATION
Cartons containing eight EVOREL CONTI patches in foil lined pouches.
The pouch comprises a 4 layer laminate including an aluminium barrier and paper exterior surface.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Do not freeze.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
31/21.8.2/0537

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
EVOREL® CONTI
Patch
Oestradiol/norethisterone
EVOREL CONTI is a matrix type transdermal patch.

Read all of this leaflet carefully before you start using EVOREL CONTI patches
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- EVOREL CONTI 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 EVOREL CONTI CONTAINS
Each EVOREL CONTI patch contains 3,1 mg oestradiol, formulated as 3,2 mg of oestradiol hemihydrate and 9,82 mg northisterone, formulated as 11,2 mg norethisterone acetate. Each patch delivers 50 micrograms of oestradiol and 170 micrograms of norethisterone (a progestogen hormone) per 24 hours.

EVOREL CONTI patches contain the following inactive ingredients:
Acrylate-vinylacetate copolymer (adhesive), guar gum (absorbent) and polyethylene terephthalate foil (backing film).

2. WHAT EVOREL CONTI IS USED FOR
EVOREL CONTI is used for hormone replacement therapy (HRT) in the treatment of symptoms of the menopause, such as hot flushes and vaginal dryness in women who still have a womb. ¨

In women who still have a womb, using oestrogen regularly without using a progestogen may cause the lining of the womb to build up and thicken, which may lead to cancer of the womb.
Adding a progestogen hormone to the oestrogen treatment prevents this build-up of the lining of the womb. That is why the EVOREL CONTI patches also contain the progestogen, norethisterone acetate.

EVOREL CONTI does not cause a regular monthly period in the majority of women.

3. BEFORE YOU APPLY EVOREL CONTI PATCHES
Do not use EVOREL CONTI if
- You are allergic (hypersensitive) to any of the ingredients in EVOREL CONTI patches (see heading "WHAT EVOREL CONTI CONTAINS" above)
- You had, have or suspect that you have breast cancer
- You have a family history of breast cancer
- You have genital tract cancer or other cancers known to be sensitive to oestrogens
- You have undiagnosed vaginal bleeding
- You are pregnant or breastfeeding
- You have liver disease or a history of liver disease as long as liver function tests have not returned to normal.
- You have or have had blood clots (thrombosis) or inflammation of veins (thrombophlebitis) or have, a family history thereof
- You have active or previous arterial thrombotic disease (e.g. stroke, heart attack)
- You have porphyria
- You have depression, which is not well controlled with treatment.
- You have had depression with previous use of oestrogen and/or progesterone/ progestogen containing medicines.

EVOREL CONTI and breast cancer:
Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. When you are using EVOREL CONTI, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any appropriate investigations.

Before you use EVOREL CONTI, tell your doctor if:
- You are known to have inherited genetic changes called "BRCA1 and/or BRCA2 genes
- You started your menstrual periods before the age of 12 years
- You have a history of non-cancerous breast diseases such as atypical hyperplasia or lobular carcinoma *in situ*
- You had any previous treatment using radiation therapy to the chest or breast
- You have been treated or exposed while in your mother's womb to a medicine called diethylstilboestrol (DES).
- That you are on treatment for depression.
- That you have had depression with previous use of oestrogen and/or progesterone/progestogen containing medicines.
- That you have a substance abuse problem.
- You have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- That you have a family history of mental disorders.
- That you have a history of physical or sexual abuse.

Depressed mood, depression and the risk of suicidality
Oestrogen and/or progesterone/progestogen containing medicines including EVOREL CONTI, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behavior (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.

If you have any of the following, you may still be able to use EVOREL CONTI, but you should discuss this with your doctor first. He/she may need to see you more regularly for monitoring purposes whilst you are using EVOREL CONTI.

If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, you should be closely supervised by your doctor as these conditions may recur or be aggravated during treatment with EVOREL CONTI.
- Leiomyoma (uterine fibroids) or endometriosis
- Risk factors for blood clots
- Risk factors for oestrogen dependent tumours, e.g. first degree relative with breast cancer
- High blood pressure
- Liver disorders (including benign tumours of liver cells)
- Diabetes mellitus
- Gall stones
- Migraine or severe headache
- Systemic lupus erythematosus (lupus)
- A history of endometrial overgrowth (endometriosis)
- Epilepsy
- Breast disease

Your doctor will give you regular medical check-ups if you have any of the following conditions:
- Fluid retention (swelling) from oestrogens, such as in EVOREL CONTI
- If you have heart or kidney dysfunction, it should be carefully monitored
- Disturbances of liver function
- History of yellow pigmentation of skin or eyes (jaundice)
- Pre-existing high cholesterol or triglycerides

If you develop any of the following conditions during whist using EVOREL CONTI, immediately inform your doctor and stop using EVOREL CONTI:
- Yellowing of the skin or eyes (jaundice) or deterioration of liver function
- Increase in blood pressure
- New migraine type of headaches
- You become pregnant

If you are not sure about any of the conditions mentioned above, please speak to your doctor.
- There is evidence that HRT, such as EVOREL CONTI may increase the risk of breast cancer in postmenopausal women receiving long-term HRT. You should not use EVOREL CONTI for more than 5 years

Ovarian cancer
- Long-term use of oestrogen containing HRT products such as in EVOREL CONTI has been associated with an increased risk of ovarian cancer.

Venous thromboembolism (blood clots)
- It is important that you have a full and thorough physical and gynaecological examination and that your own family's medical histories regarding thrombosis (blood clots) are taken before you start EVOREL CONTI.
- You should receive regular full medical examinations whilst using EVOREL CONTI.
- If you have had a blood clot in the leg or lung, a stroke or a heart attack or are bed-ridden for any reason, such as alter an operation, you may still be able to use EVOREL CONTI but your doctor should decide on this and you should have a regular medical check up with your doctor if you do use it. If, while using EVOREL CONTI, you develop symptoms of a blood clot such as unexplained pains in the chest, abdomen or legs, the patch should be removed and your doctor contacted immediately.

Heart Disease
- *Combined oestrogen-progestogen therapy such as* EVOREL CONTI: The relative risk of heart disease during use of combined oestrogen-progestogen HRT is increased.

Stroke
There is an increased risk of stroke in healthy women during treatment with HRT such as EVOREL CONTI.

Mental impairment
There is some evidence of mental deterioration in women using continuous combined HRT, such as EVOREL CONTI.

- EVOREL CONTI should not be used by children.
- EVOREL CONTI should not be used for contraception.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. Tell your doctor if you are pregnant, or think you are pregnant. You should not use EVOREL CONTI during pregnancy. You should not breastfeed when using EVOREL CONTI.
Stop using EVOREL CONTI should you fall pregnant whilst on this medication.

Taking other medicines
Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).
Some medicines can reduce the effect of EVOREL CONTI, such as, anti-epilepsy medicines (barbiturates, hydantoins, carbamazepine, meprobamate), phenylbutazone, rifampicin, rifabutin, bosentan, St. John's wort preparations (*Hypericum perforatum*) and certain medicines used for treatment of HIV infections and hepatitis, such as nevirapine and efavirenz.

EVOREL CONTI use may result in a decreased therapeutic effects and spontaneous bleeding if you use these medicines.

Oestrogen-containing oral contraceptives have been shown to significantly decrease plasma concentrations of the anti-epileptic medicine lamotrigine when co-administered. This may reduce seizure control.
Therefore, your doctor may adjust the dosage of lamotrigine if necessary.
If you are taking any of these medicines, tell to your doctor. If you are taking other medicines on a regular basis, including medicines obtained without a prescription, the use of any of these medicines together with EVOREL CONTI can cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional for advice.

4. HOW TO USE EVOREL CONTI patches
Always use EVOREL CONTI exactly as your doctor has told you.
EVOREL CONTI treatment should not be continued for longer than 5 years.

When to use the patch
There are enough hormones in each patch to last for several days but to ensure a steady supply to the body, the patches must be changed at 3 or 4-day intervals.

To make it easy to remember when this should be done, keep to the same two days every week. This will mean that one patch is on for three and the other for four days. For example, if you use your first patch on a Monday, it should be changed on Thursday and again on the following Monday.

You can work out the two days of your own schedule from the following table, starting from the first day of use:

If you put your first patch on:	Change on	Change again on
Monday	Thursday	Monday
Tuesday	Friday	Tuesday
Wednesday	Saturday	Wednesday
Thursday	Sunday	Thursday
Friday	Monday	Friday
Saturday	Tuesday	Saturday
Sunday	Wednesday	Sunday

To help you to remember your "two patch change" days, mark them as shown:
Mon Tues Wed Thur Fri Sat Sun
Thur Fri Sat Sun Mon Tues Wed

How to put the patches on
The patch should be applied to clean, dry skin but not on top of cuts, spots or other skin blemishes or on an area where you have just applied cream, moisturiser or talc.

The EVOREL CONTI patch should be applied to the skin as soon as it is removed from the wrapper and applied as described below:
(a) Tear open the wrapper, first between the "V's" along one edge and then along the other edge. Take out the patch.
(b) With the backing foil facing you, bend the patch and peel off one half of the foil. **Do not touch the sticky side of the patch** otherwise it may not stick properly.
(c) Apply the open half of the patch to your skin, remove the other half of the foil and press down the rest of the patch.
(d) Press the patch with the palm of your hand to ensure it is firmly stuck to the skin.
(e) To remove, peel away an edge of the patch and pull smoothly away from the skin.
(f) You may use soap and water to help remove any gum/glue, which may remain on your skin after patch removal.

Where to place the patch
Stick the patch onto a hairless area of skin below the waist. Most women prefer to wear the patch on the thigh or bottom. **It should never be worn on or near the breasts.** Although it can be worn underneath clothing, it should not be placed under elasticized waistbands.
The patch should not be placed on the same area of skin twice in a row.

What if the patch falls off?
Just apply a new patch and keep to your original "patch change" days.

What if I forget to change the patch?
Just change it as soon as possible and then keep to your original "patch change" days.
Forgetting a dose may increase the likelihood of breakthrough bleeding and spotting.

Can I wash, bath or shower as normal?
YES, but do not scrub too hard in case you loosen the edges of the patch.

Can I go swimming with the patch on?
YES, the patch will not be affected.

Can I exercise or play sports?
YES, but try to avoid wearing it under tight clothing or waistband.

Can I sunbathe with the patch on?
YES, but keep the patch covered to avoid direct sunlight.

What if I am allergic to the patch?
As with normal sticking plaster, allergic reactions to the patch are unlikely. However, should you have such a reaction, please consult your doctor.

Does the patch work as a contraceptive?
NO, the levels of hormone supplied by the EVOREL CONTI patch are too low for it to do this. Although menopausal women face an ever-decreasing risk of pregnancy, normal precautions should be taken during intercourse. If in doubt, talk to your doctor.

If you use more EVOREL CONTI than you should
Overdose with the patch is unlikely. Effects of too much EVOREL CONTI can be reversed simply by removal of the patch. The most common symptoms of EVOREL CONTI overdose are breast tenderness, nausea, irregular bleeding, stomach pain and/or bloating.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS
EVOREL CONTI can cause side effects.
Side effects include the following:
Frequent:
- Sudden swelling of the face or throat which may cause difficulty in swallowing or breathing. This may be a sign of an allergic reaction
- Depression
- Nervousness
- Anxiety
- Sleeplessness
- Headache
- Sensation of tingling, burning, pricking or numbness of the body
- Abnormal heart beat
- High blood pressure
- Widening of blood vessels
- Varicose veins
- Stomach pain
- Feeling sick
- Red rash
- Joint pain
- Back pain
- Menstrual disorder (Irregular, heavy or prolonged bleeding from the vagina)
- Breast pain
- Bleeding at irregular intervals
- Genital discharge
- Small, fingerlike growths of opening of vagina (cervical polyps)
- Painful periods
- Excessive proliferation of the cells of the inner lining of the womb
- Abnormally heavy and prolonged menstrual period at regular intervals
- Application site reaction – this includes sensitivity, redness, swelling and/or itchiness on the skin where the patch was placed
- Swelling may occur on the skin where the patch was placed
- Tiredness
- Pain
- Weight gain

Less frequent:
- Decreased sex drive
- Suicidal thoughts/behaviour and suicide
- Itching
- Swelling may occur on the skin where the patch is placed
- Genital/ vaginal fungal thrush
- Breast cancer
- Dizziness; epilepsy
- Formation of a blood clot inside a blood vessel,
- Frequent and loose watery stools with excessive gas in stomach or intestines
- Muscle pain
- Vaginal thrush
- Abnormal growth of breast tissue, endometrial cancer
- Mood swings
- Stroke, dizziness, migraine
- Deep vein blood clots
- Clots in the lungs
- Abdominal enlargement
- Gall stones
- Severe skin and mucous membrane rash (Stevens-Johnson Syndrome)
- Breast enlargement

If you develop skin rashes or irritation where you applied the patch, remove the patch and ask your doctor for advice. If you notice any other symptoms not listed above whilst using the patch, please tell your doctor about them.
Not all side effects reported for EVOREL CONTI are included in this leaflet. Should your general health worsen or if you experience any other untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF EVOREL CONTI
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 25 °C. Do not freeze.
Do not dispose unused medicine in drains or sewerage systems (e.g. toilets).

Other important information:
Do not use the patches:
⌦ After the expiry date shown on the label
⌦ If the protective sachet/pouch is open

7. PRESENTATION OF EVOREL CONTI
EVOREL CONTI comes in a carton pack containing eight patches in protective sealed foil-lined pouches.

8. IDENTIFICATION OF EVOREL CONTI
EVOREL CONTI patches are square shaped, transparent patches with a self-adhesive backing, which can be stuck to the skin. EVOREL CONTI is marked CEN1 and has a surface area of 16 cm^2.
In each patch the active ingredients are spread evenly in the adhesive and pass slowly through the skin into the body.

9. REGISTRATION NUMBER
EVOREL CONTI: 31/21.8.2/0537

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand 1685
South Africa
011 635 0000

11. DATE OF PUBLICATION
Date of registration: 16 February 1998
Date of most recently revised patient information leaflet: October 2020

Namibia: NS2 04/21.8.2/0244

adcock ingram

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
Skedule 4

HANDELSNAAM, STERKTE EN DOSERINGSVORM
EVOREL® CONTI
Plakker
Estradiol/noretisteroon
EVOREL CONTI is 'n matrikstipe transdermale plakker.

Lees die hele pamflet deeglik deur voordat jy begin om EVOREL CONTI te gebruik.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy nog vrae het, raadpleeg asseblief jou dokter of apteker.
- EVOREL CONTI is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

1. WAT EVOREL CONTI BEVAT
Elke EVOREL CONTI plakker bevat 3,1 mg estradiol, geformuleer as 3,2 mg estradiolhemihidraat en 9,82 mg noretisteroon, geformuleer as 11,2 mg noretisteroonasetaat. Elke plakker lewer 50 mikrogram estradiol en 170 mikrogram noretisteroon ('n progestogeenhormoon) per 24 uur.

EVOREL CONTI plakkers bevat die volgende onaktiewe bestanddele: Akrilaat-vinielasetaat-kopolimeer (kleefmiddel), guargom (absorbeerder) en poliëtileen tereftalaatfoelie (steunlaag).

2. WAARVOOR EVOREL CONTI GEBRUIK WORD
EVOREL CONTI word gebruik vir hormoonvervangingsterapie (HVT) by die behandeling van die simptome van die menopouse, soos warmgloede en vaginale droogheid by vrouens wat nog 'n baarmoeder het.

By vroue wat nog 'n baarmoeder het, kan die gereelde gebruik van estro- gene sonder om 'n progestageen te gebruik, veroorsaak dat die voering in die baarmoeder kan opbou en verdik, wat dan kan lei tot kanker van die baarmoeder. Die toevoeging van 'n progestogeenhormoon tot die estrogeenbehandeling verhoed hierdie opbouing van die voering van die baarmoeder. Om hierdie rede bevat die EVOREL CONTI plakkers ook die progestageen, noretisteroonasetaat.
By die meeste vrouens veroorsaak EVOREL CONTI nie 'n gewone maan- delikse menstruasie nie.

3. VOORDAT JY EVOREL CONTI PLAKKERS OPPLAK
Moenie EVOREL CONTI gebruik nie, indien
- Jy allergies (hipersensitief) is vir enige van die bestanddele in EVOREL CONTI plakkers nie (kyk hierbo, by die opskrif "WAT EVOREL CONTI BEVAT")
- Jy borskanker het, of vermoed dat jy dit het
- Jy het 'n familiegeskiedenis van borskanker.
- Jy kanker van die genitale weg het, of ander kankers met bekende sen- sitiwiteit vir estrogeen
- Jy ongediagnoseerde vaginale bloeding het
- Jy swanger is of borsvoed
- Jy akute lewersiekte, of 'n geskiedenis van lewersiekte het, solank die lewerfunksiewaardes nie genormaliseer het nie
- Jy tans bloedklonte (trombose), of ontsteking van die are (tromboflebitis) het, of gehad het, of as jy 'n familiegeskiedenis daarvan het
- Jy aktiewe trombotiese aarsiekte (bv. beroerte, hartaanval) het, of voor- heen gehad het
- Jy porfirie het
- Jy depressie het, wat nie goed beheer word met behandeling nie.
- Jy het depressie met vorige gebruik van estrogeen- en/of progesteroon/ progestogeenbevattende medisyne gehad.

EVOREL CONTI en borskanker:
Borskanker is meer gereeld gediagnoseer in vrouens wat die Pil gebruik as by vrouens van dieselfde ouderdom wat nie die Pil gebruik nie. Hierdie effense toename in die aantal borskankerdiagnoses verdwyn geleidelik gedurende die 10 jaar nadat die gebruik van die Pil gestop is. Wanneer jy EVOREL CONTI gebruik, moet jy bors selfondersoeke maandelikse genaamd doen. Jou dokter sal u adviseer oor wanneer jy vir borsondersoeke en enige toepaslike ondersoeke moet aanmeld.

Voordat jy EVOREL CONTI gebruik, vertel jou dokter indien:
- Dit bekend is dat jy genetiese veranderinge geërf het, "BRCA1 en/of BRCA2 gene".
- Jy jou menstruele periodes voor die ouderdom van 12 jaar begin het.
- Jy 'n geskiedenis van nie-kankeragtige borssiektes soos atipiese hiperplasie of lobulêre karsinoom in situ het nie.
- Jy enige vorige behandeling, wat bestralingterapie van die bors gebruik, gehad het.
- Jy behandel of blootgestel aan medisyne genaamd dietielstilboestrol (DES) was terwyl jy in jou moeder se baarmoeder was.
- Jy op behandeling vir depressie is.
- Jy depressie gehad het met vorige gebruik van estrogeen- en/of progesteroon/ progestageenbevattende medisyne.
- Jy 'n dwelmmisbruikprobleem het.
- Jy onderliggende psigiatriese versteuring soos posttraumatiese sresversteuring of bipolêre versteuring het.
- Jy 'n familiegeskiedenis van geestesversteurings het.
- Jy 'n geskiedenis vanf fisiese of seksuele mishandeling het.

Depressiewe bui, depressie en die risiko van selfmoord
Estrogeen- en/of progesteroon/progestageenbevattende medisyne, insluitend EVOREL CONTI, kan bui-veranderinge en depressie veroorsaak, wat ernstig kan wees. Erge depressie hou verband met 'n hoër risiko van selfmoordgedagtes/ gedrag (bv. praat oor selfmoord, ontrekking van sosiale kontak, buierigheid, behep met die dood of geweld, hopeloos voel oor 'n situasie, toenemende gebruik van alkohol/dwelms, doen selfvernietigende dinge, persoonlikheidsveranderings) en selfmoord. Indien jy buierigheid of depressie ervaar, kontak jou dokter vir advies.

As jy enige van die volgende het, kan jy EVOREL CONTI nog steeds gebruik, maar jy moet dit eers met jou dokter bespreek. Hy/sy sal jou dalk meer gereeld wil sien om jou te kan moniteer terwyl jy EVOREL CONTI gebruik.

Indien enige van die volgende toestande teenwoordig is, voorheen plaasgevind het en/of vererger het tydens swangerskap of vorige hormoonbehandeling, moet jy deeglike toesig van jou dokter ontvang, aangesien hierdie siektetoestande weer kan voorkom of vererger kan word tydens behandeling met EVOREL CONTI.
- Leiomioom (baarmoederveselspiergewasse) of endometriose
- Risikofaktore vir bloedklonte
- Risikofaktore vir estrogeengevoelige gewasse, bv. eerstegraadse familielid met borskanker
- Hoë bloeddruk
- Lewersiektes (waaronder goedaardige gewasse van die lewerselle)
- Diabetes mellitus
- Galstene
- Migraine, of ernstige hoofpyn
- Sistemiese lupus eritematose (lupus)
- 'n Geskiedenis van oorgroeiing van die endometrium (endometriose)
- Epilepsie
- Borssiekte

Jou dokter sal gereeld mediese ondersoeke op jou wil doen as jy enige van die volgende siektetoestande het:
- Vloeistofretensie (swelling) van estrogene, soos bevat in EVOREL CONTI
- Indien jy 'n versteurde hart- of nierfunksie het, moet dit noukeurig gemoniteer word
- Versteurings van die lewerfunksie
- Geskiedenis van geel pigmentasie van die vel of oë (geelsug)
- Vooraf bestaande hoë cholesterol of trigliseriede

Indien jy enige van die volgende toestande ontwikkel terwyl jy EVOREL CONTI gebruik, lig dadelik jou dokter in en hou op om EVOREL CONTI te gebruik:
- Vergeelde vel (geelsug) of agteruitgang van die lewerfunksie
- Toename in bloeddruk
- Nuwe aanvang van migraine-tipe hoofpyne
- Jy swanger raak

Indien jy nie seker is oor enige van die bogenoemde toestande nie, praat asseblief met jou dokter.
- Daar is getuienis dat HVT, soos EVOREL CONTI, die risiko van borskanker by postmenopousale vroue wat langtermyn-HVT ontvang, kan verhoog. Jy moet nie EVOREL CONTI vir meer as 5 jaar gebruik nie.

Ovariumkanker
- Langdurige gebruik van estrogeen-bevattende HVT produkte, soos EVOREL CONTI, is in verband gebring met 'n verhoogde risiko vir ova-riumkanker.

Veneuse tromboëmbolisme (bloedklonte)
- Dit is belangrik dat jy 'n volledige en deeglike fisiese en ginekologiese ondersoek ondergaan en dat die mediese geskiedenis van jou eie familie betreffende trombose (bloedklonte) in ag geneem word voordat jy met EVOREL CONTI begin.
- Jy moet gereeld volledige mediese ondersoeke ondergaan terwyl jy EVOREL CONTI gebruik.
- As jy 'n bloedklont in die been of long gehad het, 'n beroerte of 'n hartaanval kry, of om die een of ander rede bedlêend is, soos ná 'n operasie, mag dit steeds moontlik wees dat jy EVOREL CONTI kan gebruik, maar jou dokter moet hieroor besluit en jy moet jouself gereeld medies laat ondersoek as jy dit gebruik. As jy, terwyl jy EVOREL CONTI gebruik, simptome van 'n bloedklont ontwikkel, soos ontvverkliaarbare pyne in die bors, buik of bene, moet die plakker verwyder word en jou dokter dadelik gekontak word.

Hartsiekte
- *Gekombineerde estrogeen-progestageenbehandeling, soos* EVOREL CONTI: Die relatiewe risiko van hartsiekte tydens die gebruik van gekombineerde estrogeen-progestageen-HVT is hoër.

Beroerte
Daar is 'n verhoogde risiko vir beroerte by gesonde vrouens tydens behandeling met HVT, soos EVOREL CONTI.

Verstandelike belemmering
Daar is 'n mate van bewys van verstandelike agteruitgang by vroue wat gebruik maak van deurlopende gekombineerde HVT, soos EVOREL CONTI.
- EVOREL CONTI moet nie deur kinders gebruik word nie.
- EVOREL CONTI moet nie as voorbehoeding gebruik word nie.

Swangerskap en borsvoeding
Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige voordat jy hierdie medisyne gebruik.
Lig jou dokter in as jy swanger is, of dink jy is swanger. Jy moet nie EVOREL CONTI tydens swangerskap gebruik nie. Jy moet nie borsvoed terwyl jy EVOREL CONTI gebruik nie.
Hou op om EVOREL CONTI te gebruik as jy swanger raak terwyl jy op hierdie medisyne is.

Die gebruik van ander medisynes
Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit in komplementêre of tradisionele medisynes).
Sommige medisynes kan die werkwyse van EVOREL CONTI verminder, soos anti-epileptiese medisynes (barbiturate, hidantoïene, karbaamasepien, meprobamaat), feniebutasoon, rifampisien, rifabutien, bosentaan, produkte met Sint-Johanneskruid (*Hypericum perforatum*) en sekere medisynes vir die behandeling van MIV-infeksies, soos nevirapien en efavirens.

As jy hierdie medisynes gebruik kan die gebruik van EVOREL CONTI lei tot verminderde terapeutiese effekte en tot spontane bloeding.

Daar is aangetoon dat estrogeen-bevattende voorbehoedmiddels die plasmakonsentrasies van die anti-epileptiese medisyne lamotrigien beduidend verlaag wanneer dit gelyktydig toegedien word. Dit kan beheer oor toevalle verminder. Gevolglik kan jou dokter die dosis van lamotrigien aanpas, indien nodig.

As jy enige van hierdie medisynes neem, lig jou dokter in. As jy gereeld ander medisyne gebruik, insluitende medisyne wat sonder voorskrif verkry is, kan die gebruik van enige van hierdie medisynes saam met EVOREL CONTI ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige.

4. HOE OM EVOREL CONTI PLAKKERS TE GEBRUIK
Gebruik EVOREL altyd presies soos jou dokter vir jou gesê het. Behandeling met EVOREL CONTI moet nie vir langer as 5 jaar volgehou word nie.

Wanneer om die plakker te gebruik
Daar is genoeg hormone in elke plakker om vir etlike dae te hou, maar vir bestendige voorsiening aan die liggaam moet die plakkers met 3 of 4-dag tussenposes vervang word.

Om dit makliker te maak om te onthou wanneer dit gedoen moet word, bly by dieselfde twee dae elke week. Dit sal beteken dat een plakker vir drie dae, en die ander een vir vier dae op is. Byvoorbeeld, as jy jou eerste plakker op 'n Maandag opgeplak het, moet dit op Donderdag vervang word en dan weer op die volgende Maandag.
Jy kan die twee dae van jou eie skedule uitwerk vanaf die volgende tabel, vanaf die eerste dag van gebruik:

Indien jy jou eerste plakker opplak op:	Verander op	Verander weer op
Maandag	Donderdag	Maandag
Dinsdag	Vrydag	Dinsdag
Woensdag	Saterdag	Woensdag
Donderdag	Sondag	Donderdag
Vrydag	Maandag	Vrydag
Saterdag	Dinsdag	Saterdag
Sondag	Woensdag	Sondag

Om jou te help om jou "twee plakker-vervangingsdae" te onthou, merk hulle soos volg:
Ma Di Wo Do Vr Sa So
Do Vr Sa So Ma Di Wo

Hoe om die plakkers op te sit
Die plakker moet op 'n skoon, droë vel geplak word, maar nie op snye, vlekke of ander velletsels nie, of op 'n gebied waar jy pas room, bevogtiger of talk aangewend het nie.

Die EVOREL CONTI plakker moet, sodra dit uit die verpakking verwyder is, soos volg op die vel geplak word:
(a) Skeur die omhulsel oop, eers tussen die "V's" aan die een kant en dan langs die ander kant. Haal die plakker uit.
(b) Met rugkant-foelie na jou kant toe, buig die plakker en trek die een helfte van die foelie af. **Moenie raak aan die kleverige kant van die plakker** nie, anders sal dit dalk nie goed plak nie.
(c) Plak die oop helfte van die plakker op jou vel, verwyder dan die ander helfte van die foelie en druk die res van die plakker vas.
(d) Druk die plakker met jou handpalm om seker te maak dit sit stewig vas aan die vel.
(e) Om te verwyder, maak die rand van die plakker los en trek dit dan egalig af van die vel.
(f) Jy kan seep en water gebruik om te help om enige gom/lym wat op jou vel agterbly nadat die plakker af is, te verwyder.

Waar om die plakker te plaas
Plak die plakker op 'n haarlose velstreek, onder die middel. Meeste vrouens verkies om die plakker op die dy of boud te dra. **Dit moet nooit op, of naby die borste geplak word nie.** Hoewel dit onder klere gedra kan word, moet dit nie onder rekkerige gordels geplak word nie.

Die plakker moet nie twee opeenvolgende kere op dieselfde plek op die vel geplak word nie.

Wat om te doen as die plakker afval?
Plak net 'n nuwe plakker op en hou by jou oorspronklike "plakker-vervangingsdae".

Wat gebeur as ek vergeet om die plakker te vervang?
Verander dit sodra moontlik en hou dan by jou oorspronklike "plakker-vervangingsdae".
As 'n dosis vergeet word, kan dit die moontlikheid van deurbraakbloeding en spikkelbloeding verhoog.

Kan ek was, bad en stort soos gewoonlik?
JA, maar moenie te hard vryf nie, vir ingeval jy die rante van jou plakker laat loskom.

Kan ek swem met die plakker op?
JA, die plakker sal nie aangetas word nie.

Kan ek oefen of sport beoefen?
JA, maar probeer vermy om dit onder stywe klere of gordels te dra.

Kan ek sonbaai met die plakker op?
JA, maar hou die plakker toe om dit teen direkte sonlig te beskerm.

Wat gebeur as ek allergies is vir die plakker?
Soos met normale kleefpleister, is allergiese reaksies op die plakker onwaarskynlik. Indien jy so 'n reaksie het, raadpleeg egter asseblief jou dokter.

Werk die plakker as 'n voorbehoedmiddel?
NEE, die hormoonvlakke wat deur die EVOREL CONTI plakker verskaf word is te laag daarvoor. Alhoewel menopousale vroue 'n steeds-afnemende risiko loop vir swangerskap, moet normale voorsorg tydens omgang getref word. Indien jy twyfel, raadpleeg jou dokter.

Indien jy meer EVOREL CONTI gebruik as wat jy moes
Oordosering met die plakker is onwaarskynlik. Die uitwerking van te veel EVOREL CONTI kan omgekeer word deur eenvoudig die plakker te verwyder. Die mees algemene simptome van oordosering met EVOREL CONTI is teer borste, naarheid, ongereelde bloeding, maagpyn en/of buikopsetting. In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

5. MOONTLIKE NEWE-EFFEKTE
EVOREL CONTI kan newe-effekte hê. Newe-effekte kan die volgende insluit:
Dikwels:
- Skielike swelling van die gesig of keel, wat probleme om te sluk of asem te haal kan veroorsaak Dit kan 'n teken wees van 'n allergiese reaksie
- Depressie
- Senuweeagtigheid
- Angs
- Slapeloosheid
- Hoofpyn
- Gevoel van tinteling, branderigheid, stekelrigheid of gevoelloosheid van die liggaam
- Abnormale hartslag
- Hoë bloeddruk
- Verwyding van bloedvate
- Spatare
- Maagpyn
- Mislike gevoel
- Rooi uitslag
- Gewrigspyn
- Rugpyn
- Menstruele afwyking (ongereelde, swaar of uitgerekte bloeding van die vagina)
- Pynlike borste
- Bloeding met ongereelde intervalle
- Genitale afskeiding
- Klein, vingeragtige groeisels by die ingang van die vagina (servikale poliepe)
- Pynlike maandstondes
- Buitensporige proliferasie van die selle van die binnevoering van die baarmoeder
- Abnormaal swaar en langdurige maandstondes met gereelde intervalle
- Reaksie by die plek van toediening - dit behels gevoeligheid, rooiheid, swelling en/of jeukerigheid van die vel waar die plakker geplak was
- Swelling kan voorkom waar die plakker op die vel geplaas was
- Moegheid
- Pyn
- Gewigstoename

Minder dikwels:
- Verminderde seksuele drang
- Selfmoord gedagtes/gedrag en selfmoord
- Jeuk
- Swelling kan voorkom waar die plakker op die vel geplaas was
- Genitale/ vaginale sproei
- Borskanker
- Duiseligheid; epilepsie
- Vorming van 'n bloedklont binne 'n bloedvat
- Gereelde en los waterige stoelgange met buitensporige gas in die maag of derms
- Spierpyn
- Vaginale sproei
- Abnormale groei van borsweefsel, endometriumkanker
- Gemoedskommelings
- Beroerte, duiseligheid, migraine
- Diep veneuse bloedklonte
- Klonte in die longe
- Buik vergroting
- Galstene
- Erge vel- en slymvliesuitslag (Stevens-Johnson-sindroom)
- Vergrote borste

As jy veluitslag of irritasie ontwikkel waar jy die plakker opgesit het, verwyder die plakker en kry raad by jou dokter. Indien jy, terwyl jy die plakker gebruik, enige ander simptome waarneem wat nie hierbo gelys is nie, sê asseblief vir jou dokter daarvan.
Nie alle newe-effekte wat vir EVOREL CONTI aangemeld is, is by hierdie inligtingblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan, of jy enige ander ongunstige effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige.

6. BERGING EN WEGDOENING VAN EVOREL CONTI
BERE ALLE MEDISYNE BUITE BEREIK VAN KINDERS
Bewaar by of benede 25 °C. Moenie vries nie. Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

Ander belangrike inligting:
Moenie die plakkers gebruik nie:
⌦ Na die vervaldatum wat op die etiket verskyn
⌦ Indien die beskermende sakkie/omhulsel oop is nie.

7. AANBIEDING VAN EVOREL CONTI
EVOREL CONTI kom in 'n kartonpakkie met agt plakkers in beskermende verseëlde sakkies wat met foelie uitgevoer is.

8. IDENTIFIKASIE VAN EVOREL CONTI
EVOREL CONTI plakkers is vierkantig gevorm, is deursigtig met 'n selfklewende kant, wat op die vel geplak kan word. EVOREL CONTI is gemerk met CEN1 en het 'n oppervlak van 16 cm^2.

In elke plakker is die aktiewe bestanddele eweredig in die kleeflaag versprei, waarvandaan dit stadig deur die vel geabsorbeer word om in die liggaam te kom.

9. REGISTRASIENOMMER
EVOREL CONTI: 31/21.8.2/0537

10. NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER:
Adcock Ingram Limited
1 New Road, Erand Gardens
Midrand 1685
South Africa
011 635 0000

11. DATUM VAN PUBLIKASIE
Datum van registrasie: 16 Februarie 1998
Datum van mees onlangs hersiene pasiëntinligtingsblad soos goedgekeur deur die Raad: October 2020

Namibië: NS2 04/21.8.2/0244

adcock ingram