PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Evorel® Conti Transdermal Patch

Active ingredients and their quantity per dosage unit:
Each patch contains:
estradiol (as hemihydrate) 3.2 mg
norethisterone acetate 11.2 mg

Each patch of Evorel Conti releases 50 mcg estradiol and 170 mcg norethisterone acetate/24 hours.

Inactive ingredients and allergens in the preparation – see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Hormone replacement therapy (HRT) for the relief of menopausal symptoms.

Therapeutic group: a combination of estrogen and progestogen.

Menopause happens when the level of hormones produced by the ovaries goes down. This is a gradual process. During this period, the estrogen levels can go up and down. This can cause:
- Hot flushes, night sweats or mood swings
- Vaginal problems such as dryness or itching
- Uncomfortable or painful sexual intercourse.

You may experience these symptoms if you have had your ovaries taken out in an operation.
How Evorel Conti works – both hormones in the patch are continuously released.
Evorel Conti patches replace the estrogen that is normally released by the ovaries. However, in women who have a womb, taking an estrogen hormone regularly may cause thickening of the lining of the womb.
- This means it is necessary to add a progestogen hormone to the estrogen
- This supplement helps shed the thickened lining of the womb and prevent problems from happening

Most women do not have a regular monthly period with Evorel Conti. However, bleeding or spotting does usually occur in the first months until the treatment settles down.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see section 6 – "Further Information")
- You have, have ever had, or are suspected of having **breast cancer**
- You have or are suspected of having a **cancerous tumor that is made worse by estrogens** (such as endometrial cancer)
- You have **excessive thickening of the lining of the womb** (endometrial hyperplasia) which has not been treated
- You have **unexplained vaginal bleeding**
- You have or have ever had **blood clots in the veins** (thrombosis), such as in the legs (deep venous thrombosis) or in the lungs (pulmonary embolism)
- You have **blood clotting problems** (such as protein C, protein S or antithrombin deficiency)
- You have, or have ever had, **a liver disease** and your liver function tests have not yet returned to normal
- You have or recently have had a disease caused by blood clots in the arteries, such as an **angina pectoris**, a **heart attack** or a **stroke**
- You have a rare inherited blood problem called porphyria

Do not use the preparation if any of the above conditions apply to you. If you are uncertain, consult the doctor or pharmacist before using Evorel Conti. If any of the above conditions appear for the first time while taking Evorel Conti, stop using the medicine at once and refer immediately to the doctor.

Special warnings regarding use of the medicine

Medical history and medical check-ups
The use of an hormonal replacement preparation carries risks which need to be considered when deciding whether to start or continue treatment.
Experience in treating women with premature menopause (due to ovarian failure or surgery) is limited. In these cases, the risks of using HRT may be different. Consult your doctor.
Before beginning or continuing taking hormone replacement therapy, the doctor will ask you about your and your family's medical history. The doctor may decide to perform a physical examination which may include an examination of your breasts and/or an internal examination, if necessary
Once you have started using Evorel Conti, you should meet with the doctor for periodic medical check-ups (at least once a year). At these check-ups, the doctor may discuss the benefits and risks of continuing treatment with the medicine.
You should have periodic breast examinations as recommended by the doctor.
Before starting treatment, tell your doctor if you have ever had any of the following conditions, as these may return or become worse during treatment with Evorel Conti. If so, you may need periodic medical check-ups more frequently:
- Fibroids
- Growth of womb lining outside your womb (endometriosis) or a history of excessive thickening of womb lining (endometrial hyperplasia)
- Increased risk of developing blood clots [see below "Blood clots in a vein (thrombosis)"]
- Increased risk of cancer tumors related to estrogen (e.g., mother, sister or grandmother who had breast cancer)
- Hypertension
- 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 liver disorder, such as a benign liver tumor
- Fluid retention due to heart or kidney problems
- A very high level of triglycerides (fats) in the blood
- Hereditary and acquired angioedema
- Thyroid problems
- History of sudden swelling of the face or throat, which may cause difficulty in swallowing or breathing, rapid swelling of the hands and feet and stomach cramps.

You may still be able to use Evorel Conti, but first you should consult the doctor. Tell the doctor if these conditions recur or get worse during the course of treatment with Evorel Conti.
The risk of use of hormone replacement therapy in cases of premature menopause may be different. Consult the doctor regarding the risks.

Please make sure that you:
- Go for regular breast screening and cervical smear tests
- Regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Stop treatment with Evorel Conti and refer to the doctor immediately in the following situations:
- Any of the conditions mentioned above in section 2 – "Do not use the medicine if"
- Yellowing of the skin or the whites of the eyes (jaundice). These may be signs of a liver disease
- Swelling of the face, tongue and/or throat and/or difficulty swallowing or hives (rash), together with difficulty breathing, which are suggestive of angioedema
- A notable rise in blood pressure (symptoms may be: headache, tiredness, dizziness)
- Migraine-like headaches which happen for the first time
- If you become pregnant
- 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)".

Evorel 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. Talk to the doctor for advice.

In addition to the benefits, use of HRTs bears also risks. Consider the following information before starting use of, or when continuing treatment with these preparations.

The effect of hormone replacement therapy on the heart and blood circulation

Heart diseases (heart attack)
There is no evidence that HRT will prevent a heart attack.
Women over the age of 60 years who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.
Hormone replacement therapy **is not recommended** for women who have recently had heart diseases. If you have ever had a heart disease, talk to the doctor to determine whether or not you should use these preparations.

Stroke
Studies suggest that hormone replacement therapy slightly increases the risk of getting a stroke.
Other factors may increase the risk of stroke:
- Getting older
- Hypertension
- Smoking
- Drinking too much alcohol
- An irregular heartbeat

If you are worried about any of the above-mentioned factors, or if you have had a stroke in the past, please talk to the doctor regarding use of these preparations.
For women who take HRT, the risk of having a stroke is about 1.5 times higher than in women who do not take HRT. The number of extra cases of stroke due to use of HRT is higher with age.

Comparison
Looking at women in their 50s, over 5 years, on average:
- **8 out of 1,000 women not taking an HRT** are expected to have a stroke
- **11 out of 1,000 women taking an HRT** are expected to have a stroke **(3 extra cases)**

If you suffer from unexplained **migraine-type headaches**
- **Refer to a doctor as soon as possible**
- **Do not take the hormone replacement therapy any more** until your doctor says you can

These headaches may be an early warning sign of a stroke.

Blood clots in a vein (thrombosis)
The risk of **formation of blood clots in the veins** is 1.3-3 times higher in women taking HRT as compared to women not taking these preparations, especially during the first year of using them.
Blood clots can be serious, and if such a blood clot travels to the lungs, chest pain, breathlessness, fainting and even death may occur.
There is a higher likelihood of getting a blood clot in a vein with increased age and if any of the following apply to you. Inform your doctor if any of the following apply to you:
- You are overweight (BMI above 30 kg/m^2)
- You have cancer
- You are taking medicine containing an estrogen
- You have a blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- You are immobile for a long period of time because of major surgery, injury or illness (see below "*operations or check-ups")*
- You have a rare illness called systemic lupus erythematosus (SLE)

For signs of a blood clot, see above "Stop treatment with Evorel Conti and refer to the doctor immediately in the following conditions".
If any of the above-mentioned conditions apply to you, talk to the doctor whether to take an HRT.

Comparison
Looking at women in their 50s, over 5 years, on average:
- 4-7 out of 1,000 women not taking an HRT are expected to have a blood clot
- 9-12 out of 1,000 women taking an HRT containing estrogen and progestogen are expected to have a blood clot (5 extra cases)

If you have painful swelling in the leg, sudden chest pain or have difficulty breathing
- **Refer to a doctor as soon as possible**
- **Do not use the hormone replacement therapy any more** until the doctor says you can

These may be signs of formation of a blood clot.

HRT and cancer

Breast cancer
Evidence shows that taking combined estrogen-progestogen or estrogen-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 treatment, 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.

Comparison
- For women aged 50-54 who are not taking HRT, on average, 13-17 out of 1,000 will be diagnosed with breast cancer over a 5-year period.
- For women aged 50 who start taking estrogen-only HRT for 5 years, there will be 16-17 cases in every 1,000 users (i.e., an extra 0 to 3 cases).
- For women aged 50 who start taking estrogen-progestogen HRT for 5 years, there will be 21 cases in every 1,000 users (i.e., an extra 4 to 8 cases).
- For women aged 50-59 who are not taking HRT, on average, 27 out of 1,000 will be diagnosed with breast cancer over a 10-year period.
- For women aged 50 who start taking estrogen-only HRT for 10 years, there will be 34 cases in every 1,000 users (i.e., an extra 7 cases)
- For women aged 50 who start taking estrogen-progestogen HRT for 10 years, there will be 48 cases in every 1,000 users (i.e., an extra 21 cases).

Regularly check your breasts. Refer to the doctor as soon as possible if you notice any changes such as:
- Dimpling of the skin
- Changes in the nipples
- Lumps that can be seen or felt

Additionally, you are advised to join mammography screening programs. Inform the healthcare professional who is actually taking the x-ray that you use HRT, as these preparations may increase the density of the breast tissue which may affect the outcome of the mammogram. Where the density of the breast tissue is increased, mammography may not detect all lumps.

Ovarian cancer
Ovarian cancer is rare, much rarer than breast cancer.
The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer. The risk of ovarian cancer varies with age.
For example, about 2 women in 2,000 aged 50-54 who are not taking HRT will be diagnosed with ovarian cancer over a 5-year period.
For women who are taking HRT for 5 years, about 3 women in 2,000 will be diagnosed with ovarian cancer (one extra case).

Endometrial hyperplasia and endometrial cancer
Taking estrogen-only hormone replacement therapy will increase the risk of excessive thickening of the lining of the womb and endometrial cancer. The progestogen in Evorel Conti protects you from this extra risk.

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

Refer to the doctor as soon as possible.

If you have not undergone a hysterectomy, the doctor will prescribe progestogen in addition to estrogen in most cases. These may be prescribed as separate preparations, or as a combined hormone replacement preparation.
If you have undergone a hysterectomy, the doctor will discuss with you whether you can safely take an estrogen preparation without progestogen.
If you have undergone a hysterectomy because of endometriosis, any endometrium left in your body may be at risk of cancer. The doctor may prescribe an HRT that contains progestogen in addition to estrogen.
Evorel Conti contains progestogen.

Comparison
Looking at women aged 50-65 who have not undergone a hysterectomy, on average:
- **5 out of 1,000 women not taking a hormone replacement therapy** will get endometrial cancer.
- **In women taking an estrogen-only HRT, 10-60 women out of 1,000** will get endometrial cancer **(between 5 and 55 extra cases),** depending on the dosage and duration of treatment.

The addition of progestogen to an estrogen-only HRT substantially reduces the risk of endometrial cancer.

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. Refer to the doctor for consultation.
- If you have **brown patches on your face or body** (chloasma) or have a history of them, you may need to keep out of the sun or away from sunbeds (these patches may not completely disappear again).

Smoking
If you smoke, do not use the medicine without consulting the doctor. It is recommended that you quit smoking while using Evorel Conti. If you are unable to quit smoking and you are over the age of 35, consult a doctor. Smoking is a risk factor for venous thromboembolism (VTE).

Children and adolescents
The medicine is not intended for children.

Operations or check-ups
Inform the doctor that you are taking Evorel Conti if you are going to have surgery. You may need to stop using Evorel Conti about 4 to 6 weeks before the surgery to reduce the risk of a blood clots [see above "Blood clots in a vein (thrombosis)"].
The doctor will tell you when you can resume taking this kind of preparation.
If you perform a urine or blood test in a hospital or at the family doctor, please tell the doctor or the laboratory staff that you are using Evorel Conti. This is because Evorel Conti may affect the results of the tests.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Some medicines may interfere with the effect of Evorel Conti. This might lead to irregular bleeding. Especially if you are taking:
- Medicines **for epilepsy** (such as: phenobarbital, phenytoin or carbamazepine).
- Medicines for **treatment of tuberculosis** (such as: rifampicin, rifabutin).
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir or nelfinavir).
- Medicine for treatment of hepatitis C – telaprevir.
- Bosentan – a medicine for hypertension in the blood vessels of the lungs.
- **St. John's wort** (Hypericum perforatum).

Taking these medicines with Evorel Conti may stop its activity, and you may therefore suffer from bleeding, like a period, when you are not expecting it.

HRT can affect the way other medicines work:
- A medicine for epilepsy (lamotrigine), as this could lead to an increase in the frequency of seizures.
- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir) may cause an increase in liver function blood test results (increase in ALT liver enzyme) in women using combined hormonal contraceptives containing ethinylestradiol. Evorel Conti contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Evorel Conti with HCV combination regimen.

Pregnancy and breastfeeding
Do not use the preparation if you are pregnant, think you may be pregnant or might be pregnant. This is because Evorel Conti may affect the baby.
Evorel Conti is intended for women after menopause only. If you become pregnant, please contact the doctor immediately and remove the patch.
Do not use the preparation if you are breastfeeding.

Driving and use of machinery
There is no information about whether Evorel Conti affects the ability to drive or use machines. Please check to see how the medicine affects you before driving or using heavy tools or operating machinery.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the medicine.
The doctor will aim to prescribe the lowest dose to treat your symptoms for the shortest time necessary. Speak to the doctor if you think the dose is too strong or not strong enough.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
Change the patches twice a week.
Start a new pack of Evorel Conti immediately after finishing the previous pack, without a break between packs.
The doctor is aiming to reduce the symptoms with the lowest dosage for the shortest amount of time.

Do not exceed the recommended dose. Do not swallow. For external use only.

When to start treatment with Evorel Conti
Treatment can be started at any time if:
- You have not been using another HRT

Put an Evorel Conti patch on at the end of a treatment cycle or one week after you finish using another HRT preparation if:
- You are changing from an HRT preparation that caused you menstrual bleeding

If you are using another HRT:
- The day to start Evorel Conti treatment will depend on the other type of HRT you have been using.

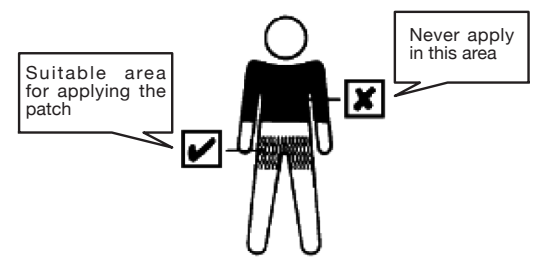
Please refer to the doctor if you are not sure which type of HRT you are using.

Changing the Evorel Conti patches
- Change the patches twice a week to give your body a steady supply of hormones. There is enough hormone in each patch to last for several days.
- Change the patch on the same two days every week. This will mean that one patch is on for three days and the second patch for four days.
- For example, if you applied your first patch on a Monday, put on the second patch on Thursday and again on the following Monday. You can work out your two changing days from the following table:

If you put your first patch on:		Change to the next patch 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

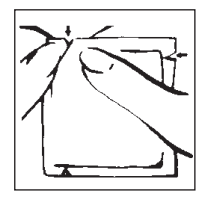
To help you remember your two patch change days, mark them on the back of the pack. They are written on the pack like this:

Where to apply the patches
Apply the patch onto a hairless area of skin below the waistline. Most women prefer to wear the patch on the thigh or buttocks.
- Do not apply on or near the breasts
- Do not apply on skin with cuts, spots or anywhere the skin is irritated
- Do not apply on skin which has been recently treated with cream, moisturizer or talc before applying the patch
- Do not apply a new patch in the same area where the previous patch was placed
- The patch can be applied under clothing, in areas where the clothing is loose
- Do not apply the patch under elastic or rubber bands
- Apply the patch on clean, dry and cool skin immediately after taking it out of the protective pouch

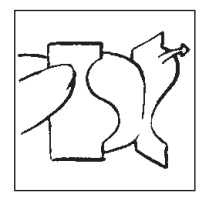


Applying a patch
Do not use a patch if the protective pouch is already open.

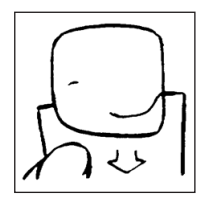
Step 1: Open and Peel
- Using the notches as a guide, tear along the 2 edges of the pouch and remove the patch.



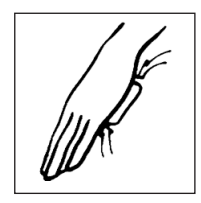
- Hold the patch with its cover (the aluminum-type foil) facing you, fold the patch gently and remove one part of the aluminum foil covering the patch. Avoid touching the sticky side of the patch. It may impair its adhesive properties.



Step 2: Apply and Press
- Apply the exposed half of the patch to your skin.
- Peel off the second half of the aluminum-type foil and press the second half of the patch onto the skin.



- Press the patch onto the skin using the palm of your hand to ensure that it is firmly stuck to the skin.



Removing a patch
- Peel the edges of the patch away from the skin and remove it by pulling gently.
- Fold the patch in half, so that the adhesive side is inward.
- Place the patch in a household waste bin, out of the reach of children and animals.
- Do not dispose of used patches into the toilet bowl.

After removing the patch, a little glue may remain on your skin. The glue will disappear over time, or baby oil can be used to remove the remaining glue.

If a patch falls off
Replace the patch that has fallen off with a new patch, but keep to your original patch change days. If you have just had a shower or bath, wait until your skin cools before applying a new patch.
Talk to the doctor if you need more patches.

If you forget to change the patch
Change the patch as soon as you remember and then continue with your regular change days. The patch change days do not change. In this case, you may get some spotting or period-like bleeding during this time.

If you used a higher dosage of Evorel Conti than recommended
It is unlikely that you will get too much of the hormones in Evorel Conti. The most common symptoms of having too much estrogen or progestogen in your body are:
- Tender breasts
- Nausea or vomiting
- Unexpected vaginal bleeding
- Feeling depressed
- Tiredness
- Acne
- Growth of body or facial hair

These symptoms, which are due to excess estrogen or progestogen, are reversible upon removal of the patch. Consult the doctor or pharmacist before using another patch.

Contraception while using Evorel Conti
The levels of hormone in the preparation are too low to be used as a contraceptive.
Use non-hormonal contraceptive methods (such as a condom, diaphragm or ring) until your periods have completely stopped.

Everyday activities
- You can shower or take a bath as normal. Do not scrub the skin around the patch too hard, as this can loosen the edges of the patch.
- You can go swimming. The patch will not be affected by this activity.
- You can exercise. Do not apply the patch under a tight garment or rubber bands.
- You can sunbathe, but be sure to keep the patch under a garment, out of direct sunlight.

Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, please consult with the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Evorel Conti may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
The following diseases are reported more often in women taking HRT preparations, as compared to women not taking such preparations:
- Breast cancer
- Abnormal growth or cancer of the lining of the womb
- Ovarian cancer
- Blood clots in the veins of the legs or lungs
- Heart diseases
- Stroke
- Probable memory loss if HRT began over the age of 65

For further information about these side effects, refer to section 2 in the leaflet.

Take off the patch and refer to a doctor immediately if you notice or suspect any of the following conditions. You may need urgent medical treatment
- Sudden swelling of the face or throat which causes difficulty in swallowing or breathing, rapid swelling of the hands and feet and stomach cramps
- Blood clots (thrombosis) (affects less than 1 in 1,000 users) or stroke (unknown frequency)
- Yellowing of the skin or whites of the eyes (jaundice), or other liver problems
- Migraine-type headaches that occur for the first time or more frequently (affects less than 1 in 100 users)
- An increase in blood pressure (affects less than 1 in 10 users)
- Breast or ovarian cancer, endometrial cancer or hyperplasia (long, heavy or irregular menstruation)
- Widespread rash with skin peeling and blistering in the mouth, eyes and genitals (Stevens-Johnson syndrome) (unknown frequency)
- Seizures (affects less than 1 in 1,000 users)

Inform the doctor if you notice any of the following effects while using Evorel Conti

Very common side effects – effects that occur in more than one user in ten
- Irritation, itchiness, redness and rash on the skin where the patch is applied

Common side effects – effects that occur in 1-10 in 100 users
- Allergic reaction (hypersensitivity)
- Inability to sleep
- Feeling depressed, nervous or anxious
- Headache
- Rapid heartbeats (palpitations)
- Varicose veins
- Flushing, skin reddening
- Breast pain
- Numb or tingling hands or feet
- Nausea
- Diarrhea
- Stomachache
- Pain, including pain in the back or joints
- Painful periods
- Vaginal discharge
- Irregular, heavy or prolonged vaginal bleeding, even after intercourse
- Water retention or build-up of fluid under the skin (edema)
- Tiredness
- Weight gain

Uncommon side effects – effects that occur in 1-10 in 1,000 users
- Vaginal thrush
- Lower than usual libido
- Wind
- Itchy skin
- Rash
- Swelling of the hands and feet (peripheral edema)
- Muscle pain

Side effects of unknown frequency (effects whose frequencies have not been determined yet):
- Mood swings
- Feeling dizzy
- Bloated feeling
- Gallstones
- Fuller breasts

The following side effects have been reported with other combined HRTs:
Very common side effects – effects that occur in more than 1 user in 10
- Tender breasts

Common side effects – effects that occur in 1-10 in 100 users
- Mood changes
- Indigestion
- Acne
- Dry skin
- Extreme pain (e.g., pain in the back, arms, legs, wrists, ankles)
- Severe contractions of the uterus
- Vaginal infection (white or yellowish discharge from the vagina)

Uncommon side effects – effects that occur in 1-10 in 1,000 users
- Dizziness
- Nausea
- Skin discoloration
- Abnormal liver function blood tests

Rare side effects – effects that occur in 1-10 in 10,000 users
- Gallstones
- Muscle weakness
- Benign growths in the uterus smooth muscle
- Cysts close to the Fallopian tubes

Very rare side effects – effects that occur in less than 1 user in 10,000
- Yellowing of the skin, itching, dark-colored urine

Side effects of unknown frequency (effects whose frequencies have not been determined yet)
- Hair loss

The following effects have been reported in association with other hormonal replacement therapy
- Gallbladder disease
- Various skin disorders:
  - Discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma)
  - Erythema nodosum – painful reddish skin nodules
  - Erythema multiforme – skin and mucosal rash or sores
  - Purpura – skin rash with red or purple colored spots
- Loss of memory; see section 2 "other conditions"
- Dry eyes
- Change in composition of tears

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 25°C.
- Store in the original package.
- Do not use the patches if the pouch containing the patch is open.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains
  Duro-Tak (acrylate vinylacetate copolymer), guar gum (meyprogat), hostaphan MN 19 (polyethylene terephthalate foil)
- What the medicine looks like and the contents of the package
  Evorel Conti is provided in a memory package that contains 8 patches. CEN1 is marked on the patch itself.
  The patches are square with rounded edges. The patches are transparent, with an adhesive side that is applied to the skin. Each patch comes in a closed pouch and the patch size is 16 cm^2.
- Registration holder and address:
  Truemed Ltd.,10 Beni Gaon St., Poleg Industrial Park P.O Box 8105, Netanya 4250499.
- Manufacturer and address:
  Theramex Ireland Limited, Dublin, Ireland
- This leaflet was revised in November 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  121-50-29726

PL-1049 04-10.23
IPS THX 3925