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Package leaflet: Information for the user

ESTRAMON® 100 µg/24 h, transdermal patch

estradiol

Read all of this leaflet carefully before you start using this medicine because it contains important information.

- 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 observe 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 ESTRAMON 100 is and what it is used for.
2. What you need to know before you use ESTRAMON 100.
3. How to use ESTRAMON 100.
4. Possible side effects.
5. How to store ESTRAMON 100.
6. Contents of the pack and other information.

1 What ESTRAMON 100 is and what it is used for.

ESTRAMON 100 is a preparation for *Hormone Replacement Therapy, HRT*). It contains the female sex hormone estrogen.

ESTRAMON 100 is used for women after the menopause whose last menstrual cycle (menopause) ended at least 12 months previously.

ESTRAMON 100 is used to:

Relieve symptoms after the menopause

During the menopause, production of the body's own estrogen decreases. This may cause symptoms such as hot flashes in the face, neck, and chest. ESTRAMON 100 alleviates such symptoms that occur after the menopause. ESTRAMON 100 will only be prescribed to you if your symptoms significantly affect your everyday quality of life.

Preventing osteoporosis

After the menopause, some women's bones can become brittle (osteoporosis). You should discuss all available treatment options with your doctor. You can use ESTRAMON 100 to prevent the development of osteoporosis after the menopause if you are at increased risk of osteoporosis-related fractures and other medicines are not suitable for you.

There is only limited experience regarding treatment of women over 65 years of age.

2 What you need to know before you use ESTRAMON 100.

Medical history and regular checkups

Hormone replacement therapy is associated with certain risks that should be considered before deciding to start or continue treatment.

Experience with the treatment of women with premature menopause (due to ovarian dysfunction or surgical removal) is limited. If you have premature menopause, the risks of hormone replacement treatment may differ from those of other women. Please consult your doctor about this.

Before you start (or restart) hormone replacement treatment, your doctor will obtain your own medical history and that of your family. Your doctor will decide whether a physical examination is necessary. If necessary, this may include an examination of the breasts and/or an abdominal examination.

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Once you have started hormone replacement therapy, you should see your doctor regularly (at least once a year) for checkups. During these examinations, please discuss the benefits and risks associated with continuing ESTRAMON 100 therapy with your doctor.

Please have regular screening examinations of your breasts as recommended by your doctor.

Do not use ESTRAMON 100

if any of the following conditions apply to you. If you are not sure whether this is the case, please talk to your doctor before using ESTRAMON 100.

Do not use ESTRAMON 100 if

- you are or you have previously been suffering from **breast cancer** or if you are suspected of having breast cancer
- you are suffering from a **type of cancer whose growth is dependent on estrogens**, such as cancer of the uterine lining (endometrium) or a corresponding suspicion
- **vaginal bleeding of unknown cause** occurs
- there is untreated **excessive thickening of the uterine lining** (endometrial hyperplasia)
- you have or have previously had a **blood clot in a vein (thrombosis)**, for instance in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism).
- You are suffering from a **blood clotting disorder** (for instance, protein C, protein S or antithrombin deficiency)
- you are or have previously been suffering from a disorder caused by blood clots in the arteries, such as B. **heart attack, stroke, or sudden tightness and pain in the chest** (angina pectoris)
- you are suffering from or have previously suffered from a **hepatic disorder** and your liver function values have not yet normalized
- you are suffering from a rare, hereditary blood disorder known as porphyria
- you have an **allergy** (intolerance) to **estradiol**, soy, peanuts, or any of the other ingredients of this medicine listed in Section 6.

If any of the above conditions occur for the first time while using ESTRAMON 100, stop treatment immediately and consult your doctor without delay.

Warnings and precautions

Talk to your doctor before if you have ever been affected by any of the health problems listed below, as these may recur or worsen during treatment with ESTRAMON 100. In the following cases you should visit your doctor more often for checkups:

- benign tumours in the uterus (fibroids)
- growth of the uterine lining outside the uterus (endometriosis) or previous excessive growth of the uterine lining (endometrial hyperplasia)
- increased risk of blood clotting (see ‘venous blood clots [thromboses]’)
- increased risk of estrogen-dependent cancer (if, for instance, your mother, sister, or grandmother had breast cancer)
- high blood pressure
- hepatic disorders, for instance a benign hepatic tumour
- diabetes
- gallstones
- migraines or severe headaches
- immune system disorder that affects many organ functions of the body (systemic lupus erythematosus [SLE])
- epilepsy
- asthma
- disorder that affects the eardrum and the hearing (otosclerosis)
- very high blood lipid levels (triglycerides)
- fluid retention as a result of cardiac or renal disorder
- congenital (hereditary) or acquired angioedema

You must discontinue treatment immediately and talk to a doctor

if any of the following disorders or situations occurs during hormone replacement therapy:

- disorders mentioned in the section ‘Do not use ESTRAMON 100’
- yellowing of your skin or the whites of your eyes (jaundice). This may be indicative of a hepatic disorder.

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- swelling of the face, the tongue and/or the throat, respectively difficulty swallowing, or hives associated with breathing problems indicating angioedema.
 - significant increase in blood pressure (symptoms may include headaches, fatigue, and dizziness)
 - migraine-like headaches occurring for the first time
 - if you get pregnant
 - if you notice any signs of blood clots, such as
 - painful swelling and redness of the legs
 - sudden chest pain
 - shortness of breath
- Additional information is found under ‘venous blood clots (thromboses)’.

Please note: ESTRAMON 100 is not a contraceptive. If less than 12 months have passed since your last menstrual cycle or if you are under 50 years of age, it may be necessary to use additional methods of contraception. Ask your doctor for advice.

Hormone replacement therapy and cancer

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

The risk of excessive thickening of the uterine lining (endometrial hyperplasia) and cancer of the uterine lining (endometrial cancer) increases during estrogen monotherapy.

Using/taking a gestagen in addition to the estrogen therapy for at least 12 days during each 28-day cycle protects you from this additional risk. Thus, if your uterus is still intact, your doctor will also prescribe a gestagen. If your uterus has been removed (hysterectomy), talk to your doctor about whether or not you can safely use ESTRAMON 100 without additionally taking/using a gestagen.

An average of 5 in 1,000 women who still have a uterus and who are not using any hormone replacement therapy will be diagnosed with cancer of the uterine lining between the ages of 50 and 65. In contrast, among women with an intact uterus who are undergoing hormone replacement treatment with an estrogen monopreparation, 10 to 60 cases of cancer of the uterine lining in 1,000 women are diagnosed between the ages of 50 and 65, depending on the dose and the duration of treatment (i.e., between 5 and 55 additional cases).

ESTRAMON 100 contains a higher estrogen dose than other estrogen monopreparations for hormone replacement therapy. The risk of developing cancer of the uterine lining while using ESTRAMON 100 together with a gestagen is not known.

Unexpected bleeding

While using ESTRAMON 100, bleeding will occur once a month (so-called withdrawal bleeding). However, if you experience unexpected bleeding or spotting outside of your menstrual period that continues

- beyond the first 6 months of treatment
- and starts after you have been using ESTRAMON 100 for more than 6 months
- after discontinuation of treatment,

please consult your doctor as soon as possible.

Breast cancer

The available data show that hormone replacement therapy (HRT) with a combination of estrogen and gestagen or estrogen monotherapy for HRT increases the risk of breast cancer. The additional risk depends on the duration of HRT and is evident within 3 years of use. After discontinuing HRT, the additional risk decreases over time; this risk, however, may persist for 10 years or more if you have used HRT for more than 5 years.

For comparison

Women between 50 and 54 years of age who do not use HRT are diagnosed with an average of 13 to 17 cases of breast cancer in 1,000 women over a 5-year period.

Among women at the age of 50 starting HRT with an estrogen monopreparation for a 5-year period, there are 16 to 17 cases in 1,000 users (i.e., 0 to 3 additional cases).

Among women aged 50 starting HRT with estrogen and gestagen for a 5-year period, there are 21 cases in 1,000 users (i.e., 4 to 8 additional cases).

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Women aged 50 to 59 who are not using any HRT are diagnosed with an average of 27 cases of breast cancer in 1,000 women over a 10-year period.

Among women aged 50 starting HRT with an estrogen monopreparation for a 10-year period, there are 34 cases in 1,000 users (i.e., 7 additional cases).

Among women aged 50 starting HRT with estrogen and gestagen for a 10-year period, there are 48 cases in 1,000 users (i.e., 21 additional cases).

Inspect your breasts regularly. Consult your doctor if you notice any changes in your breasts, such as

- indentations (dents) in the skin
- changes of the nipples
- lumps that you can see or feel

If you have the opportunity to participate in the early detection program for breast cancer (mammography screening program), you should take advantage of this offer. Please inform the specialist carrying out the mammogram that you are taking hormone replacement medication. Drugs taken in conjunction with hormone replacement therapy may enhance the density of the breast tissue and thus influence the result of the mammogram. If the density of the breast tissue is increased, it may not be possible to detect all of the changes.

Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of estrogen monopreparations or combined estrogen-gestagen preparations for hormone replacement therapy is associated with a slightly increased risk of developing ovarian cancer. The risk of developing ovarian cancer changes with age.

Among women aged 50 to 54 who are not using any HRT, an average of approximately 2 cases in 2,000 women are diagnosed with breast cancer over a 5-year period. Among women using hormone replacement therapy for more than 5 years, there are about 3 cases in 2,000 users (i.e., about 1 additional case).

Cardiovascular effects of hormone replacement therapy

Venous blood clots (thromboses)

The risk of **blood clots forming in the veins** (thromboses) is about 1.3 to 3 times higher among women using hormone replacement therapy than among non-users. The risk is particularly high during the first year of use.

Blood clots may have serious consequences. If a blood clot travels to the lungs, it can cause chest tightness, shortness of breath, fainting spells, or even death.

You are more likely to develop a blood clot as you get older and if any of the following conditions apply to you. Please talk to your doctor if any of the following situations apply to you:

- if you are unable to walk for a prolonged period of time due to major surgery, injury, or illness (see also Section 3 under the heading ‘if you are scheduled for surgery’)
- if you are considerably overweight (BMI>30 kg/m²)
- if you are suffering from a coagulation disorder that requires long-term medication to prevent blood clots
- if a close relative of yours has ever had a blood clot in a leg, the lung, or other organ
- if you are suffering from systemic lupus erythematosus (SLE)
- if you have cancer.

Regarding signs of blood clots, please see ‘you must discontinue treatment immediately and talk to a doctor’.

For comparison

Looking at women in their 50s who are using hormone replacement therapy, an average of 4 to 7 in 1,000 women may be expected to develop a venous blood clot during the next 5 years.

Among women in their 50s who have been using hormone replacement therapy with an estrogen monopreparation for 5 years, there are 9 to 12 cases of thrombosis in 1,000 users (i.e., 5 additional cases).

Among women in their 50s whose uterus has been removed and who have been using hormone replacement therapy with an estrogen monopreparation for 5 years, there are 5 to 8 cases of thrombosis in 1,000 users (i.e., 1 additional case).

Cardiac disorder (heart attack)

There is no evidence of hormone replacement therapy preventing a heart attack.

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Women over 60 years of age who are using combined hormone replacement therapy with estrogen and gestagen are slightly more likely to develop a cardiac disorder than those who are not using hormone replacement therapy. The risk of developing heart disease is not increased among women whose uterus has been removed and who are using only estrogens.

Stroke

The risk of stroke is about 1.5 times higher among women using hormone replacement therapy than among non-users. The number of additional strokes resulting from hormone replacement therapy increases with age.

For comparison

Looking at women in their 50s who are not using hormone replacement therapy, 8 strokes in 1,000 women can be expected over a 5-year period. Among women in their 50s using hormone replacement therapy, there are 11 cases in 1,000 users (i.e., 3 additional cases).

Other disorders

- Hormone replacement therapy does not prevent memory disorders. There is some evidence of an increased risk of memory disorders among women who are above 65 years of age at the start of hormone replacement therapy. Ask your doctor for advice.
- Patients with impaired kidney or heart function:
Estrogens may cause fluid retention in the body; thus, if you are suffering from heart or kidney dysfunction, you should be monitored carefully. If you are suffering from severe renal dysfunction, you should be closely monitored because the circulating estrogen levels in the blood are expected to increase.
- Patients with a certain lipid metabolism disorder (hypertriglyceridemia):
If you have elevated blood lipid levels (triglycerides), your blood lipid levels should be closely monitored during ESTRAMON 100 therapy, because in rare cases a sharp rise in blood triglycerides with subsequent inflammation of the pancreas has been reported in connection with estrogen therapy.
- It is known that contact sensitization may occur with all skin applications. Although this is extremely rare, it may lead to severe allergic reactions if you continue to use the medicine.

Paediatric population

ESTRAMON 100 should not be used in children.

Using ESTRAMON 100 in combination with other medicines

Certain medicines can impair the effect of ESTRAMON 100. This may cause irregular bleeding. These include the following medicines:

- Medicines against **epilepsy** containing, for instance, phenobarbital, phenytoin, or carbamazepine
- Medicines against **tuberculosis** containing, for instance, rifampicin or rifabutin
- certain medicines for the treatment of **HIV infections** containing, for instance, nevirapine, efavirenz, ritonavir, or nelfinavir
- herbal medicines containing **St. John's wort** (*hypericum perforatum*)
- other medicines for the treatment of infections that contain, for instance, ketoconazole or erythromycin.

Hormone replacement therapy can influence the mode of action of other medicines:

- Medicines for epilepsy (lamotrigine), as this may lead to an increase in the frequency of seizures.
- The ombitasvir/paritaprevir/ritonavir combination therapy with or without dasabuvir, as well as the glecaprevir/pibrentasvir therapy against the hepatitis C virus (HCV) may cause liver values in blood tests to rise (increase in the liver enzyme ALT) in women using CHD therapy with ethinylestradiol. ESTRAMON 100 contains estradiol instead of ethinylestradiol. It is not known whether an increase in the liver enzyme ALT may occur when using ESTRAMON 100 together with this combination therapy against HCV.

Tell your doctor or pharmacist if you are taking/using other medicines, if you have recently taken/used other medicines, or if you intend to take/use other medicines; even if they are non-prescription medicines, herbal preparations, or natural remedies. Your doctor will be happy to advise you.

Laboratory tests

If you need to have a blood test, tell your doctor or laboratory staff that you are using ESTRAMON 100, as this medicine may affect the results of certain laboratory tests.

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Pregnancy and lactation

Pregnancy

ESTRAMON 100 is only intended for use by postmenopausal women. If you get pregnant, discontinue the use of ESTRAMON 100 and consult your doctor.

Breastfeeding

Do not use ESTRAMON 100 while breastfeeding.

Effects on ability to drive and use machines

ESTRAMON 100 is not known to influence the ability to drive or to operate machines.

3 How to use ESTRAMON 100.

Always make sure to use this medicine exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

Your doctor will try to prescribe the lowest dose required to treat your symptoms for as briefly as possible. Please talk to your doctor if you have the impression that the effect of ESTRAMON 100 is too strong or too weak.

How to use ESTRAMON 100.

ESTRAMON 100 may be used continuously (without a break) or cyclically (21 days of use, followed by a 7-day break). In women with an intact uterus, treatment with ESTRAMON 100 must be combined with an appropriate dose of a gestagen (to be prescribed by the doctor) for at least 12-14 days during each 28-day cycle (see also Section 2).

Addition of a gestagen is not recommended for women whose uterus has been removed, except in cases where growth of the uterine lining outside the (endometriosis) has been diagnosed (see also Section 2).

Uninterrupted use of ESTRAMON 100 is possible in women after removal of the uterus or if the estrogen deficiency symptoms reappear strongly during the treatment-free period.

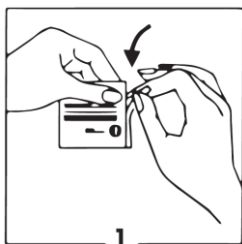
Irregular bleeding or spotting may occur during the first few months of treatment. If you have heavy bleeding or if the bleeding or spotting continues beyond the first few months of treatment, please inform your doctor so that your treatment can be adjusted if necessary (see Section 2, 'unexpected bleeding').

Method of administration

For transdermal application (sticking to the skin)

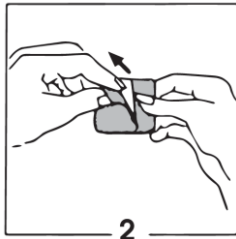
An ESTRAMON 100 patch is applied twice a week, i.e., the used patch is replaced with a new one every 3 or 4 days.

The spot where the transdermal patch is applied should be changed with each new transdermal patch. The most suitable areas for the patch are areas of skin below the waistline where the skin does not wrinkle much. ESTRAMON 100 must not be applied on or near the breasts! The selected skin area must be clean, free of grease, dry, and undamaged. The transdermal patch should be applied as soon as it is removed from the sachet. If possible, please do not touch the adhesive surface.



1. The transdermal patches are individually wrapped. Immediately before use, tear open the wrapping at the incision near a corner of the sachet and remove the transdermal patch without damaging it. (Figure 1)

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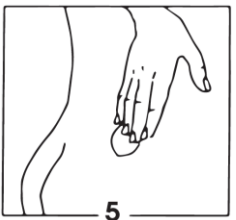
- Carefully bend the transdermal patch up and down along the slit line until the peel-off film detaches from the adhesive surface of the transdermal patch along the punched line. Now peel off part of the slit peel-off foil from the back of the patch. (Figure 2)



- Attach the released adhesive surface to a healthy, cleaned area of skin on the lower abdomen or the back of the hip. (Figure 3)



- Then slightly lift the adjacent part of the transdermal patch, remove the remaining peel-off film and stick the transdermal patch on completely. (Figure 4)



- After application, press the transdermal patch firmly down with the palm of your hand and hold it for about 10 seconds. (Figure 5)

Do not expose the transdermal patch to direct sunlight. ESTRAMON 100 also adheres well to the skin when bathing, showering, or during physical activity.

However, if a patch comes off prematurely (before the end of 3 or 4 days), either partially or completely, please replace it with a new transdermal patch.

Check whether the unsatisfactory adhesion of the patch is due to application errors. In rare cases, however, adhesion may be impaired by individual skin conditions.

Start of therapy

If you

- are not currently using hormone replacement therapy or if you have used estrogen - possibly together with a gestagen - without interruption, you may start ESTRAMON 100 therapy any day.

If you

- have used estrogen regularly for 21 days - on the last 12-14 days together with a gestagen - and then paused treatment for 7 days; or if you
- have used the estrogen without interruption but have also used a gestagen for the last 12-14 days during each 28-day cycle,

you should end the current treatment cycle before starting ESTRAMON 100 treatment.

The first day after the end of the previous therapy (with continuous use) or the first day after the treatment break (with cyclical use) is a suitable time to start ESTRAMON 100 treatment.

If you have used a larger amount of ESTRAMON 100 than you should

If you have used larger quantities, you must consult a doctor.

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Possible signs of an overdose include nausea, vomiting, a tight sensation in the breasts, and vaginal bleeding.

If there are any signs of an overdose, ESTRAMON 100 should be removed. Any necessary treatment should be based on the symptoms.

If you have forgotten to use ESTRAMON 100

Do not apply a double dose if you have forgotten the previous application.

If you have - accidentally - forgotten to change the transdermal patch after the 3rd or 4th day, please change it immediately. The subsequent patch change should then be on the regular day.

Skipped doses increase the likelihood of breakthrough bleeding or spotting.

Please inform your doctor if you wish to interrupt your treatment for an extended period of time.

If you discontinue ESTRAMON 100 treatment

You should not interrupt or discontinue ESTRAMON 100 therapy without consulting your doctor. If you stop this treatment, there might be some withdrawal bleeding.

If you are scheduled for surgery

If you are to undergo surgery, please inform the operating doctor that you are using ESTRAMON 100. 4 to 6 weeks before the planned operation you may have to stop using ESTRAMON 100 in order to reduce the risk of thrombosis (see Section 2, 'Venous blood clots [thrombosis]'). Please consult your doctor; he or she can tell you when to continue using ESTRAMON 100.

If you have any further questions about using this medicine, ask your doctor or pharmacist.

4 Possible side effects.

This medicine - like all medicines - may have certain side effects, but these do not necessarily have to occur in your case.

The following disorders have been reported more frequently by women using hormone replacement therapy than by non-users:

- breast cancer
- excessive growth or cancer of the uterine lining (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- memory impairment (probable dementia) if hormone replacement therapy started above 65 years of age

For additional information on these side effects please see Section 2.

Some side effects can be severe

If you observe one or more of the following symptoms, you need immediate medical attention:

- sudden chest pain
- chest pain radiating to an arm or the neck
- shortness of breath
- painful swelling and redness of the legs
- yellowish discolouration of the eyes and facial skin, darkening of the urine, itching (jaundice)
- unusual vaginal bleeding or spotting (breakthrough bleeding) after prolonged use of ESTRAMON 100 patches or after discontinuing ESTRAMON 100 therapy
- changes to the breast, in particular indentations in the skin, changes to the nipples and lumps that you can see or feel (breast cancer)
- painful menstrual periods
- unclear migraine-like headaches

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Stop using ESTRAMON 100 and consult your doctor immediately if you detect one or more of the above symptoms. Please pay attention to the risks generally associated with hormone replacement therapy (see Section 2 'Warnings and precautions').

Other side effects

In addition, the following side effects have been reported in conjunction with ESTRAMON 100:

Very common (may affect more than 1 in 10 patients)

- headaches
- skin reactions at the application site (including skin irritation, burning, rash, dry skin, bleeding, bruising, inflammation, swelling, skin pigmentation, hives and blistering)
- breast tightness and breast pain
- painful menstrual periods, menstrual disorders

Common (may affect up to 1 in 10 patients)

- depression
- nervousness
- mood swings
- sleeplessness
- drowsiness
- nausea
- indigestion
- diarrhea
- abdominal pain
- bloating sensation
- abdominal fullness
- increased appetite
- acne
- rash
- dry skin
- itching
- back pain
- enlarged breasts
- heavy menstrual bleeding
- viscous white to yellowish vaginal discharge
- irregular vaginal bleeding
- strong uterine contractions
- vaginitis
- excessive thickening of the uterine mucosa (*endometrial hyperplasia*)
- pain
- weakness
- fluid retention (*edema*) in the limbs (hands and feet)
- weight change

Uncommon (may affect up to 1 in 100 patients)

- anxiety
- migraine
- dizziness
- visual problems
- dry eyes
- increase in blood pressure
- palpitations of the heart
- vomiting
- skin discolouration
- joint pain

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- muscle cramps
- increase in specific liver enzymes

Rare (may affect up to 1 in 1,000 patients)

- intolerance
- change in sexual desire
- tingling or numbness in hands and feet
- venous blood clots
- gallstones
- change in liver function and bile flow
- hair loss
- muscle weakness
- uterine leiomyoma
- fallopian tube cysts
- cervical polyps
- secretion from the mammary gland
- allergic reactions such as rashes
- loss of appetite

Very rare (may affect up to 1 in 10,000 patients)

- hives
- signs of a severe allergic reaction (including difficulty breathing, swelling of the face, tongue, throat or skin, dizziness and hives)
- reduced tolerance to carbohydrates
- involuntary movements of the eyes, head and neck
- difficulties wearing contact lenses
- severe skin changes
- excessive hair growth
- worsening of porphyria
- nosebleeding

Not known (cannot be estimated from the available data)

- breast cancer
- blood clots
- pain in the extremities
- abnormal liver function values
- allergic skin inflammation
- lumps in the breast (non-cancerous)

Soybean oil (Ph. Eur.) may cause allergic reactions.

The following side effects were reported in conjunction with other preparations used for hormone replacement therapy:

- biliary disorders
- various skin disorders
 - skin discolouration, especially on the face and neck, so-called pregnancy spots (chloasma)
 - painful, reddish skin nodules (erythema nodosum)
 - rash with disc-shaped redness or inflammation (erythema multiforme)

Reporting of side effects

If you observe 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 to the

Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
Abt. (Dept.) Pharmakovigilanz (Pharmacovigilance)
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: <https://www.bfarm.de>

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. By reporting any side effects that may occur, you may contribute to making more information about the safety of this medicine available.

5 How to store ESTRAMON 100.

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date mentioned on the folding box and the sachet under 'expiry date' or 'use by' date. The expiry date is the last day of the respective month.

Storage conditions

Do not store above 30 °C.

Special precautions for disposal

After use, the ESTRAMON 100 patch must be folded up (adhesive surface facing inwards!).

Never throw medicines in the waste water (e.g., don't flush them down the toilet or sink). Ask your pharmacy how to dispose of the medicine when you have finished using it. This will help protect the environment. For further information please see <https://www.bfarm.de/arzneimittelentsorgung>.

6 Contents of the pack and other information.

What ESTRAMON 100 contains

The active substance is: estradiol

1 transdermal patch with a patch size of 40 cm² contains:
8.26 mg estradiol hemihydrate, corresponding to 8 mg estradiol

Average estradiol release per day:
100 micrograms

The other ingredients are:

Matrix: Poly[(2-ethylhexyl)acrylate-co-methylacrylate-co-acrylic acid-co-(2,3-epoxypropyl)methacrylate] (62.2:32.0:5.7:0.03), *RRR-alpha*-tocopherol preparation (USP) (contains soybean oil [Ph.Eur.])

Carrier film: Polyethylene terephthalate

Protective film: Polyethylene terephthalate, siliconised

Appearance of ESTRAMON 100 and content of the pack

ESTRAMON 100 is a transparent oval transdermal patch with a protective film (remove before use) and two functional layers: an estradiol-containing self-adhesive matrix layer and a carrier film.

ESTRAMON 100 is available in pack sizes of 6, 18, and 24 transdermal patches.

It is possible that not all pack sizes will be placed on the market.

Pharmaceutical company and manufacturer

Hexal AG

Industriestraße 25

83607 Holzkirchen

Telephone: (08024) 908-0

Fax: (08024) 908-1290

Email: service@hexal.com

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