Package leaflet: Information for the user

Estriol 0.5 mg/g vaginal cream
For use in adult women

estriol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Estriol 0.5 mg/g vaginal cream is and what it is used for
2. What you need to know before you use Estriol 0.5 mg/g vaginal cream
3. How to use Estriol 0.5 mg/g vaginal cream
4. Possible side effects
5. How to store Estriol 0.5 mg/g vaginal cream
6. Contents of the pack and other information

1. What Estriol 0.5 mg/g vaginal cream is and what it is used for

Estriol 0.5 mg/g vaginal cream belongs to a group of medicines called vaginal hormone replacement therapy (HRT). It is used to relieve menopausal symptoms in the vagina such as dryness or irritation. In medical terms this is known as ‘vaginal atrophy’. It is caused by a drop in the levels of oestrogen in your body. This happens naturally after the menopause.

Estriol 0.5 mg/g vaginal cream works by replacing the oestrogen which is normally produced in the ovaries of women. It is inserted into your vagina, so the hormone is released where it is needed. This may relieve discomfort in the vagina.

2. What you need to know before you use Estriol 0.5 mg/g vaginal cream

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

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

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

Once you have started on Estriol 0.5 mg/g vaginal cream, you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Estriol 0.5 mg/g vaginal cream.

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

Do not use Estriol 0.5 mg/g vaginal cream,
if any of the following applies to you. If you are not sure about any of the points below, talk to your doctor before using Estriol 0.5 mg/g vaginal cream.

Do not use Estriol 0.5 mg/g vaginal cream if:
- you have or have ever had breast cancer, or if you are suspected of having it
- you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- you have any unexplained vaginal bleeding
- you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- you have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency)
- you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- you have or have ever had a liver disease and your liver function tests have not returned to normal
- you have a rare blood problem called “porphyria” which is passed down in families (inherited)
- you are allergic to estriol or any of the other ingredients of this medicine (listed in section 6)

If any of the above conditions appear for the first time while using Estriol 0.5 mg/g vaginal cream, stop using it at once and consult your doctor immediately.

Warnings and precautions
Tell your doctor if you have or have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Estriol 0.5 mg/g vaginal cream. If so, you should see your doctor more often for check-ups:
- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see “Blood clots in a vein (thrombosis)”)
- increased risk of getting oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headache
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- hereditary and acquired angioedema

Stop using Estriol 0.5 mg/g vaginal cream and see a doctor immediately,
if you notice any of the following when using HRT:
- any of the conditions mentioned in the “Do not use Estriol 0.5 mg/g vaginal cream” section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease.
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema

- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs
  - sudden chest pain
  - difficulty in breathing

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

Note
Estriol 0.5 mg/g vaginal cream is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer
Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)
Taking oestrogen-only HRT tablets for a long time can increase the risk of developing cancer of the womb lining (the endometrium).

It is uncertain whether there is a similar risk when Estriol 0.5 mg/g vaginal cream is used for repeated or long-term (more than one year) treatments. However, Estriol 0.5 mg/g vaginal cream has been shown to have very low absorption into the blood, therefore, the addition of a progestagen is not necessary.

If you get bleeding or spotting, it is usually nothing to worry about, but you should make an appointment to see your doctor. It could be a sign that your endometrium has become thicker.

The following risks apply to hormone replacement therapy (HRT) medicines which circulate in the blood. However, Estriol 0.5 mg/g vaginal cream is for local treatment in the vagina and the absorption into the blood is very low. It is less likely that the conditions mentioned below will get worse or come back during treatment with Estriol 0.5 mg/g vaginal cream, but you should see your doctor if you are concerned.

Breast cancer
Evidence suggests that using Estriol 0.5 mg/g vaginal cream does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if Estriol 0.5 mg/g vaginal cream can be safely used in women who had breast cancer in the past.

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

Additionally, you are advised to join mammography screening programs when offered to you.

Ovarian cancer
Ovarian cancer is rare – much rarer than breast cancer. The use of oestrogen-only HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2 000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2 000 users (i.e. about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of blood clots in the veins is about 1.3 to 3 times higher in HRT users than in non-users, especially during the first year of using it.

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

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3 "If you need to have surgery")
- you are seriously overweight (BMI > 30 kg/m²)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer

For signs of a blood clot, see "Stop using Estriol 0.5 mg/g vaginal cream and see a doctor immediately".

Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1 000 would be expected to get a blood clot in a vein.
For women in their 50s who have been using oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1 000 users (i.e. 1 extra case).

Heart disease (heart attack)

For women using oestrogen-only therapy there is no increased risk of developing a heart disease.

Stroke

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

Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1 000 would be expected to have a stroke over a 5-year period. For women in their 50s who are using HRT, there will be 11 cases in 1 000 users (i.e. 3 extra cases).

Other conditions

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

Note

The simultaneous use of Estriol 0.5 mg/g vaginal cream and condoms made of latex can reduce tensile strength and thus impair the safety of condoms.

Children and adolescents

There is no relevant use of Estriol 0.5 mg/g vaginal cream in children and adolescents.

Other medicines and Estriol 0.5 mg/g vaginal cream

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription, herbal medicines or other natural products. This is because this medicine can affect the way some other medicines work. In addition, some other medicines can affect the way this medicine works.

Tell your doctor or pharmacist if you are taking any of the following:
- medicines for epilepsy - such as barbiturates, hydantoins and carbamezapine.
- medicines for infections - such as griseofulvin and rifamycins.
- medicines for viral infections - such as nevirapine, efavirenz, ritonavir or nelfinavir.
- herbal preparations containing St John's wort (Hypericum perforatum) - a herbal medicine used for depression.
- one of the following medicines: corticosteroids, succinylcholine,theophyllines or troleandomycin.

Tell your doctor if you have Hepatitis C and you are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Taking the combination of these drugs with some oestrogen-containing products may cause increases in liver function blood test results (increase in ALT liver enzyme); the risk of this happening with this medicine is currently unknown.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.
If you have a vaginal infection, your doctor may also prescribe a medicine to treat the infection.

Operations
Tell your doctor you are using this medicine if you are going to have surgery. You may need to stop using HRT about 4 to 6 weeks before the operation to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.

Pregnancy and breast-feeding
Estriol 0.5 mg/g vaginal cream is for use in postmenopausal women only. If you become pregnant, stop using Estriol 0.5 mg/g vaginal cream and contact your doctor.
- Do not use this medicine if you are pregnant or might become pregnant. This is because it may affect the baby.
- Do not breast-feed if you are using this medicine.

Driving and using machines
Estriol 0.5 mg/g vaginal cream has no influence on the ability to drive and use machines.

Estriol 0.5 mg/g vaginal cream contains cetostearyl alcohol
May cause local skin reactions (e.g. contact dermatitis).

3. How to use Estriol 0.5 mg/g vaginal cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- If you have had your womb and ovaries removed, you can start using this medicine straight away.
- If you have never used HRT before or if you are changing over from a period-free HRT, you can also use this medicine straight away.
- If you are changing over from another type of HRT where you have a period, start taking this medicine one week after you finish the other HRT.

How much to use
In general, the recommended dose during the first three weeks of treatment is 1 g of the product per day administered with the applicator. Thereafter, 1 g should be administered twice a week.

Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

How should the cream be used?
Estriol 0.5 mg/g vaginal cream is best used in the evening before going to bed. Use the applicator to insert the cream into your vagina as follows:

1. Wash your hands thoroughly.
2. Unscrew the tube cap.
3. Screw the open end of the applicator tube onto the thread of the tube, so that the entire thread of the tube is in the applicator tube.
4. Fill the applicator with cream by pressing on the tube. The dose can be read off at the scale on the plunger. The amount is correct when 1 g line mark on the plunger is flush with the top of the applicator tube (see Figure 1).
5. Unscrew the applicator tube from the tube and close the tube tightly again.
6. Insert the applicator into your vagina while lying down (on your back with slightly bent legs) or standing up (like when inserting a tampon). Carefully insert the applicator as far as possible. Push on the plunger to insert the cream into your vagina (see Figure 2).
7. Remove the emptied applicator from your vagina without pulling on the plunger as otherwise some of the cream may be sucked back into the applicator tube.

It is recommended that you use panty liners after applying Estriol 0.5 mg/g vaginal cream, as some excess may leak out.

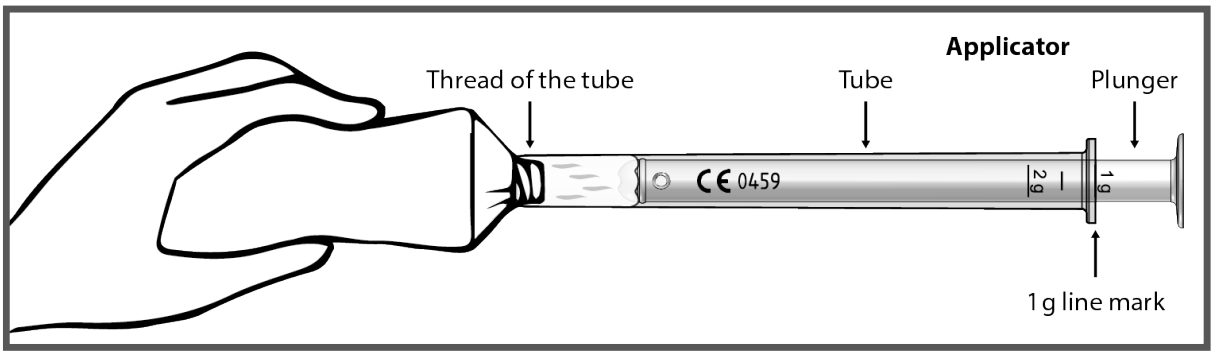


Figure 1: Applicator tube

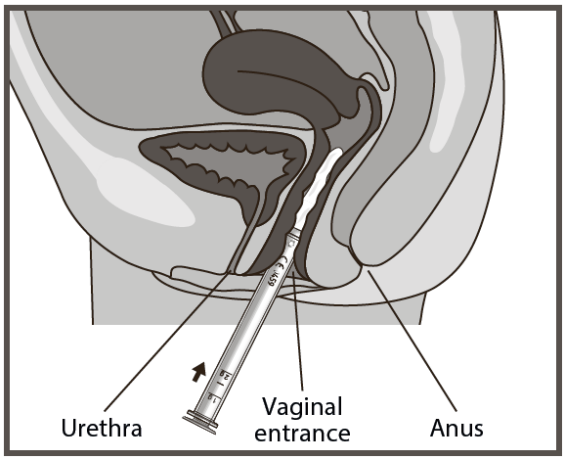


Figure 2: Insertion

Cleaning the applicator after use
The applicator is reusable. Clean it as follows after use:
- separate the tube and plunger
- clean the plunger and applicator tube in warm water
- allow to dry in the air
- reassemble the tube and plunger prior to the next use

If you use more Estriol 0.5 mg/g vaginal cream than you should
The oestrogen dose in Estriol 0.5 mg/g vaginal cream is low and it only acts locally in the vagina, therefore an overdose is unlikely to occur.

If you forgot to use Estriol 0.5 mg/g vaginal cream
Do not use a double dose to make up for a forgotten dose, instead:
- During daily use within the first weeks of treatment: Continue treatment with the usual dosing schedule.
- During twice-weekly use: Make up for the forgotten dose as soon as possible.

If you need to have surgery
If you are going to have surgery, tell the surgeon that you are using Estriol 0.5 mg/g vaginal cream. You may need to stop using Estriol 0.5 mg/g vaginal cream 4 to 6 weeks before the surgery to reduce the risk of a blood clot (see section 2 "Blood clots in a vein (thrombosis)"). Ask your doctor when you can start using Estriol 0.5 mg/g vaginal cream again.

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

4. Possible side effects

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

The following diseases are reported more often in women using HRT medicines which circulate in the blood compared to women not using HRT. These risks apply less to vaginally administered treatments such as Estriol 0.5 mg/g vaginal cream:
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- stroke
- probable memory loss if HRT is started over the age of 65

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

The following side effects may occur when using Estriol 0.5 mg/g vaginal cream

Uncommon *(may affect up to 1 in 100 people)*
- painful breast tenderness (mastodynia) during the first weeks of treatment (this symptom normally subsides)
- feeling of vaginal heat or itching
- weight gain due to fluid retention in the body
- increased blood pressure
- nausea or other gastrointestinal symptoms

Rare *(may affect up to 1 in 1 000 people)*
- uterine bleeding (either during or after withdrawal of the treatment)
- (migraine-like) headaches

Very rare *(may affect up to 1 in 10 000 people)*
- leg cramps or "heavy legs"
- allergic skin reactions (with itching, redness, swelling)

The following side effects have been reported with other HRTs
- gallbladder diseases
- various skin disorders:
  - discolouration of the skin, especially of the face or neck known as pregnancy patches (chloasma)
  - painful reddish skin nodules (erythema nodosum)

- rash with target-shaped or circular reddening or sores (erythema multiforme)

If irritation of the skin and mucous membranes occurs, use Estriol 0.5 mg/g vaginal cream less frequently or discontinue its use.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Estriol 0.5 mg/g vaginal cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and tube after 'EXP'. The expiry date refers to the last day of that month.

After first opening, this medicine in the 30 g tube can be used for 1 year and in the 50 g and 100 g tube for 3 years, but not exceeding the expiry date.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Estriol 0.5 mg/g vaginal cream contains
- The active substance is estriol. 1 g vaginal cream contains 0.5 mg estriol.
- The other ingredients are cetostearyl alcohol, macrogol 20 glycerol monostearate, glycerol monostearate (E471), isopropyl myristate, carbomer, sodium hydroxide (E524), purified water, phenoxyethanol.

What Estriol 0.5 mg/g vaginal cream looks like and contents of the pack
Estriol 0.5 mg/g vaginal cream is a white cream for vaginal use.

Estriol 0.5 mg/g vaginal cream is available in aluminium tubes of 30 g, 50 g and 100 g. The pack also contains a CE certified applicator. Not all pack sizes may be marketed.

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