

Package leaflet: Information for the user
Estriol Cream
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 symptoms are the same as yours
- If you get 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 Cream is and what it is used for
2. What you need to know before you use Estriol Cream
3. How to use Estriol Cream
4. Possible side effects
5. How to store Estriol Cream
6. Contents of the pack and other information

1. What Estriol Cream is and what it is used for

The name of your medicine is Estriol Cream.

Estriol Cream contains a medicine called estriol. This is the new name for oestriol - the medicine itself has not changed.

Estriol is a hormone known as an oestrogen. It belongs to a group of medicines called hormone replacement therapy (HRT).

What Estriol Cream is used for

Estriol Cream is used for vaginal problems caused by a lack of the hormone oestrogen.

- Estriol Cream replaces the hormone oestrogen in the vaginal area when your body is not producing enough
- This happens most often during or after the menopause (see 'What is the menopause?')

What is the menopause?

Women produce oestrogen hormones from their ovaries throughout their adult life. These hormones are important in sexual development and control of the menstrual cycle.

The menopause happens when the level of hormones produced by the ovaries goes down. This is a gradual process. During this time the levels of oestrogen can go up and down. This can cause the following symptoms:

- Vaginal dryness or itching
- Uncomfortable or painful sexual intercourse

You may get the same symptoms if you have had your ovaries taken out in an operation. This is called a 'surgical menopause'.

2. What you need to know before you use Estriol Cream

Do not use Estriol Cream if you:

- Are allergic to soya or peanuts. Estriol Cream contains peanut oil (arachis oil). See 'Important information about some of the ingredients of Estriol Cream'
- Are allergic to any of the other ingredients in Estriol Cream (listed in section 6 below)
- Have ever had or think you may have breast cancer
- Have a cancer that is made worse by oestrogens such as cancer of the lining of the womb (endometrial cancer)
- Have ever had blood clots (thrombosis)
- Have an abnormality of your clotting system that makes you more prone to develop blood clots
- Have or have recently had blocked arteries (arterial thrombo-embolic disease) that gave you angina or a heart attack
- Have a blood problem called 'porphyria'
- Have abnormal vaginal bleeding which has not been explained
- Have thickening of the lining of your womb (endometrial hyperplasia) which has not been treated
- Have acute liver disease or a history of liver disease which is not completely resolved
- Have or have ever had breast cancer, or if you are suspected of having it

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Estriol Cream.

Warnings and precautions

Check with your doctor or pharmacist before using Estriol Cream if:

- You are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Estriol Cream can damage the rubber and stop them working properly. Talk to your doctor about using another type of contraception while you are using this medicine.

Medical check-ups

Before taking HRT, your doctor should ask about you and your family's medical history. Your doctor may decide to examine your breasts or your stomach and may do an internal examination. They will only do this if it is necessary for you or if you have any special concerns.

Once you have started on HRT, see your doctor for regular check-ups (every three months). At these check-ups, your doctor may discuss the benefits and risks of continuing to take HRT.

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

Tell your doctor if you have ever had any of the following. You may need above checks more often.

- A problem caused by growth of the womb lining:
 - Inside the womb (fibroids)
 - Outside the womb (endometriosis)
- Increased risk of blood clots (see 'Blood clots')

- An increased risk of cancers related to oestrogens e.g. a family history of breast cancer (see 'Breast cancer' below)
- High blood pressure (hypertension)
- Liver problems
- Diabetes
- Gallstones
- Migraine or severe headaches
- Systemic lupus erythematosus (SLE). This is an allergic condition that causes joint pain, skin rashes and fever
- Epilepsy
- Asthma
- Bone formation in the ear (otosclerosis)
- Heart or kidney problems
- High levels of fats called 'triglycerides' in your blood (hypertriglyceridaemia)

Operations or tests

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

If you visit a hospital or your family doctor for a blood or urine test, tell them that you are using Estriol Cream. This is because this medicine may affect the results of the test.

As well as benefits, HRT has some risks. Consider the following when deciding to take or continue HRT.

HRT will not help to prevent heart disease.

Studies have shown that there was no increase in heart disease in women without a womb using oestrogen-only HRT.

If you get a pain in your chest that spreads to your arm and neck

- See a doctor as soon as possible
- Do not use any more HRT until your doctor says you can

This pain may be a sign of heart disease.

Stroke

The risk of having a stroke due to a blood clot is up to 1.5 times higher with HRT. Other things that can increase the risk of stroke include:

- Getting older
- High blood pressure
- Smoking
- Drinking too much alcohol
- An irregular heartbeat

If you are worried about any of these things or if you have had a stroke in the past, talk to your doctor to see if you should take HRT.

How likely is a stroke?

Looking at women in their 50s, on average, over 5 years:

- In women not taking HRT - 8 in 1000 would be expected to have a stroke

- In women taking HRT - 11 in 1000 would be expected to have a stroke (i.e. an extra 3 cases)

If you get migraine-type headaches which you cannot explain

- See a doctor as soon as possible
- Do not use any more HRT until your doctor says you can

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

Blood clots

HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis or DVT), by up to 3 times, especially during the first year of taking it.

These blood clots are not always serious. However, if a clot travels to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called pulmonary embolism or PE.

The risk of a blood clot increases with age. In addition, you are more likely to get a blood clot if:

- You are very overweight
- You have had a blood clot before
- Any of your close family have had blood clots
- You are pregnant or just had a baby
- You have had one or more miscarriages
- You have any blood clotting problem that needs treatment with a medicine such as warfarin
- You are off your feet for a long time because of major surgery, injury or illness
- You have a rare illness called SLE
- You have cancer

If any of these things apply to you, talk to your doctor to see if you should take HRT.

How likely is a blood clot?

Looking at women in their 50s, on average, over 5 years:

- In women not taking HRT - 7 in 1000 would be expected to get a blood clot
- In women taking oestrogen-only HRT tablets - 8 in 1000 would be expected to get a blood clot (i.e. an extra 1 case)

If you get painful swelling in your leg, sudden chest pain or have difficulty breathing

- See a doctor as soon as possible
- Do not use any more HRT until your doctor says you can

These may be signs of a blood clot.

HRT and cancer

The following risks apply to **hormone replacement therapy (HRT)** medicines which circulate in the blood. However Estriol, 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, but you should see your doctor if you are concerned.

Breast cancer

Women who have breast cancer or are suspected of having breast cancer or have had breast cancer in the past should not take HRT.

Evidence suggests that **using Estriol does not** increase the risk of breast cancer in **women who had no breast cancer in the past. It is not known if Estriol can be safely used in women who had breast cancer in the past.**

Your risk of breast cancer is also higher if:

- You have a close relative (mother, sister or grandmother) who has had breast cancer
- You are very overweight

How likely is breast cancer?

Looking at women between the ages of 50 and 65, on average, over 5 years:

- In women not taking HRT - 9-12 in 1000 will get breast cancer
- In women taking oestrogen-only HRT, there will be around an extra 1-2 cases per 1,000

If you notice any changes in your breast, such as:

- Dimpling of the skin
- Changes in the nipple
- Any lumps you can see or feel

Make an appointment to see your doctor as soon as possible

Endometrial cancer (cancer of the lining of the womb)

Taking oestrogen-only HRT tablets for a long time can increase the risk of cancer of the lining of the womb (the endometrium). It is possible there may be a similar risk with oestrogen cream used for repeated treatments or over a long time. You do not need to take a separate progestogen with Estriol Cream.

If you get breakthrough bleeding or spotting, it is usually nothing to worry about, especially in the first few months of taking HRT. However, if it carries on for more than a few months, or starts after you have been using Estriol Cream for a while, or carries on after you have stopped using Estriol Cream, you should make an appointment to see your doctor. It could be a sign that your endometrium has become thicker.

How likely is endometrial cancer?

Looking at women who still have a uterus and who are not taking HRT - on average 5 in 1,000 will be diagnosed with endometrial cancer.

For women who take oestrogen-only HRT, the number will be 2-12 times higher, depending on the dose and how long they take it. Even after they stop taking oestrogen-only HRT, they will be at higher risk for at least 10 years.

Ovarian cancer

Ovarian cancer (cancer of the ovaries) is very rare, but it is serious. It can be difficult to diagnose. This is because there are often no obvious signs of the disease. Some studies have suggested that taking oestrogen-only HRT for more than 5 years may slightly increase the risk of ovarian cancer by 1 extra case per 2,500 women. It is not yet known whether Estriol Cream increases the risk in the same way.

Tell your doctor if these illnesses return or get worse while you are using Estriol Cream.

Other medicines and Estriol Cream

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Medicines for epilepsy such as phenobarbital, phenytoin or carbamazepine
- Medicines for infections such as rifampicin, rifabutin, nevirapine or efavirenz
- Medicines for HIV infection called ritonavir and nelfinavir
- Bosentan - for high blood pressure in the blood vessels of the lungs
- St. John's Wort - for depression

Taking these medicines with Estriol Cream can stop Estriol Cream from working as well as it should and may cause bleeding from your womb.

- A medicine for epilepsy called lamotrigine. Using Estriol Cream with lamotrigine could affect control of your epilepsy.

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant, think you may be pregnant or might become pregnant. This is because it may affect the baby. Do not use this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

There is no information about whether Estriol Cream affects your ability to drive or use machines. See how this medicine affects you before you drive or use any tools or machines.

Important information about some of the ingredients of Estriol Cream

- Estriol Cream contains peanut oil (arachis oil). Do not use Estriol Cream if you are allergic to peanuts or soya. See 'Do not use Estriol Cream if' above
- Estriol Cream also contains benzoic acid (E210). This can irritate your skin, eyes, eyelids, mouth and nostrils if it comes into contact with them.

3. How to use Estriol Cream

Estriol Cream should be used in the vagina of adult women. Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Estriol Cream comes with a plastic applicator that you screw on to the tube. It will help you to put the right amount into your vagina.

Unless your doctor tells you otherwise, you should:

- Start by using one applicator of Estriol Cream each evening

When your symptoms improve, your doctor may recommend that you:

- Use one applicator of Estriol Cream twice a week

How to apply the cream

1. Remove the cap from the tube. Use the top of the cap to pierce the metal seal on the tube
2. One end of the applicator has a plunger. Screw the other end of the applicator onto the tube
3. Squeeze the tube so that the applicator barrel is completely filled with cream. This will push the plunger out



4. Unscrew the filled applicator and replace the cap on the tube
5. Lie down with your knees bent and spread apart
6. Gently insert the open end of the applicator well into your vagina
7. Push the plunger firmly but gently. Empty the cream into your vagina by pushing the plunger as far as it will go



8. Keep the plunger firmly pressed down. Grip the applicator by the barrel and remove the empty applicator
9. Wash your hands afterwards
10. Use a sanitary towel to stop your clothes getting stained

Cleaning the applicator

After each use:

- Pull the plunger out of the barrel with a sharp tug
- Clean with mild soap and warm water (not boiling water)
- Rinse well



Putting the applicator back together

- Put the tip of the plunger back into the barrel. Push the plunger firmly

If you lose or break your applicator you can get a new one from a pharmacist. Ask for the Gynest Vaginal Applicator.

When to stop using Estriol Cream

- See your doctor after 3 months to see if you need to continue treatment

- Estriol Cream should be used at the lowest dose and for the shortest period of time for your symptoms

If you swallow Estriol Cream

If a large amount of the cream is eaten or swallowed talk to a doctor or go the nearest hospital casualty department straight away.

If you forget a dose

Apply the missed dose when you remember. Do not use Estriol Cream more than once on any one day.

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

If you take more than the dose recommended by this leaflet or your doctor

Wash out the cream. Too much oestrogen therapy may cause breast pain or tenderness, nausea, spotting, abdominal cramps and/or bloating. If you are worried or have any unusual symptoms you should contact your doctor.

4. Possible side effects

Like all medicines, Estriol Cream can cause side effects, although not everybody gets them.

Stop using Estriol Cream and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden swelling of the face or throat which may cause difficulty in swallowing or breathing. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people
- Blood clots (thrombosis), a heart attack or stroke (see section 2 'Before you use Estriol Cream')
- New or unusual migraine-type headaches, with or without disturbed vision
- Yellowing of the skin or whites of the eyes (jaundice), or worsening of liver problems
- A significant increase in your blood pressure
- endometrial cancer or ovarian cancer (see section 2 'Before you use Estriol Cream') Pregnancy
- If you start to have any of the conditions listed above under 'Do not use Estriol Cream if:'.

Other side effects of oestrogen treatment:

In the reproductive and urinary system

- Break-through bleeding
- Vaginal discharge
- Needing to pass urine more often or pain on passing urine (cystitis)
- Pre-menstrual tension syndrome (PM1)

In the breasts

- Breast tenderness and pain

In the stomach

- Feeling sick (nausea), being sick (vomiting)
- Feeling bloated, stomach pain or stomach cramps
- Problems with a gland on the underside of the liver called the 'gallbladder'

In the skin

- Patches of darkened skin, small red marks on the skin, red painful swellings or bruising on the legs

In the nervous system and brain

- Migraine or severe headaches made worse
- Depression
- Dementia (loss of memory) over the age of 65

In other parts of the body

- Fast or irregular heart beats (palpitations)
- Leg pain

If any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 Cream

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use Estriol Cream after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not use Estriol Cream if you notice that the tube seal is missing or broken.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Estriol Cream contains

The active substance in Estriol Cream is estriol.

Estriol Cream contains 0.01% estriol.

The other ingredients are benzoic acid (E210), glyceryl monostearate, arachis oil (peanut oil), glycerin, glutamic acid, purified water.

What Estriol Cream looks like and contents of the pack

Estriol Cream is a white to yellowish-white cream. It comes in tubes of 80g.

The product licence is held by:
Marlborough Pharmaceuticals Ltd,

Sovereign House,
Miles Gray Road,
Basildon, Essex,
SS14 3FR
United Kingdom

Estriol Cream is made by:
PHARBIL Waltrup GmbH, Im Wirringen 12, D-45731,
Waltrup, Germany.

For information in large print, tape, CD or Braille, telephone 01279 406759.

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