

Gynest Cream

Estriol

Read all of this leaflet carefully before you start using this medicine.

- 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. 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 and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1 What Gynest is and what it is used for

The name of your medicine is Gynest cream. It is called 'Gynest' in this leaflet.

Gynest 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 estrogen. It belongs to a group of medicines called hormone replacement therapy (HRT).

What Gynest is used for

Gynest is used for vaginal problems caused by a lack of the hormone estrogen.

- Gynest replaces the hormone estrogen 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?' below)

What is the menopause?

Women produce estrogen 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 estrogen 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 Before you use Gynest

Do not use Gynest if:

- You are allergic to soya or peanuts. Gynest contains peanut oil (arachis oil). See 'Important information about some of the ingredients of Gynest' below
- You are allergic to any of the other ingredients in Gynest (listed in section 7 below)
- You have ever had or think you may have breast cancer
- You have ever had a cancer that was made worse by estrogens (such as endometrial cancer)
- You have ever had blood clots (thrombosis)
- You have ever had blocked arteries (arterial thrombo-embolic disease) that gave you angina or a heart attack
- You have a blood problem called 'porphyria'

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 Gynest.

Take special care with Gynest

Check with your doctor before using Gynest if:

- You have ever had vaginal bleeding which you could not explain
- The lining of your womb has ever got thicker (endometrial hyperplasia)
- You have ever had liver problems

You may still be able to use Gynest, but you should discuss this with your doctor first.

Check with your doctor or pharmacist before using Gynest if:

- You are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Gynest 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 these 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' in section 3 below)
- A family history of increased risk of cancers related to estrogens (see 'Breast cancer' in section 3 below)
- High blood pressure (hypertension)
- 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)

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

Taking other medicines

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 Gynest can stop Gynest from working as well as it should.

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

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 a 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 Gynest. This is because this medicine may affect the results of the test.

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 or using machines

There is no information about whether Gynest 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 Gynest

- Gynest contains peanut oil (arachis oil). Do not use Gynest if you are allergic to peanuts or soya. See 'Do not use Gynest if' above

- Gynest also contains benzoic acid (E210). This can irritate your skin, eyes, eyelids, mouth and nostrils if it comes into contact with them

3 Safety of HRT

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

Heart disease

HRT is not recommended for women who have had heart disease recently. If you have ever had heart disease, talk to your doctor to see if you should be taking HRT.

HRT will not help to prevent heart disease.

Studies with one type of HRT (containing a progestogen, and a different estrogen to the one in Gynest) have shown that women may be slightly more likely to get heart disease during the first year of taking that type of HRT. For other types of HRT (like Gynest) the risk is likely to be similar. However, this is not yet certain.

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

Research suggests that HRT slightly increases the risk of having a stroke. 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 - 3 in 1000 would be expected to have a stroke
- In women taking HRT - 4 in 1000 would be expected to have a stroke

Looking at women in their 60s, on average, over 5 years:

- In women not taking HRT - 11 in 1000 would be expected to have a stroke
- In women taking HRT - 15 in 1000 would be expected to have a stroke

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), 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.

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 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

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 - 3 in 1000 would be expected to get a blood clot
- In women taking HRT - 7 in 1000 would be expected to get a blood clot

Looking at women in their 60s, on average, over 5 years:

- In women not taking HRT - 8 in 1000 would be expected to get a blood clot
- In women taking HRT - 17 in 1000 would be expected to get a blood clot

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.



3 Safety of HRT (continued)

Breast cancer

Women who have breast cancer or have had breast cancer in the past should not take HRT.

Taking HRT slightly increases the risk of breast cancer. The risk is also slightly increased if you have a later menopause.

- Postmenopausal women taking estrogen-only HRT for 5 years - the risk is about the same as for a woman of the same age who is still having periods over that time and not taking HRT

For all kinds of HRT, the extra risk of breast cancer goes up the longer you take it. However, it returns to normal within about 5 years after stopping HRT.

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 aged 50, on average, over the next 15 years:

- In women not taking HRT- 32 in 1000 will get breast cancer
- In women taking estrogen-only HRT at age 50 and take it for 5 years, between 33 and 34 in 1000 will get breast cancer
- In women taking estrogen-only HRT for 10 years - 37 in 1000 will get breast cancer

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.

4 How to use Gynest

Gynest 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.

Gynest 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 Gynest each evening

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

- Use one applicator of Gynest 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
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5 Possible side effects

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

Stop using Gynest 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 3 'Safety of HRT' above)
- Migraine-type headaches for the first time
- Yellowing of the skin or whites of the eyes (jaundice), or other liver problems
- An increase in your blood pressure
- Breast cancer, endometrial cancer or ovarian cancer (see section 3 'Safety of HRT' above)

Endometrial cancer (cancer of the lining of the womb)

Taking estrogen-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 estrogen cream used for repeated treatments or over a long time. You do not need to take a separate progestogen with Gynest.

If you get breakthrough 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.

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 estrogen-only HRT for more than 5 years may increase the risk of ovarian cancer. It is not yet known whether other kinds of HRT increase the risk in the same way.

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 Gynest

- See your doctor after 3 months to see if you need to continue treatment
- Gynest should be used at the lowest dose and for the shortest period of time for your symptoms

If you swallow Gynest

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 Gynest more than once on any one day.

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

6 How to store Gynest

Keep out of the reach and sight of children.

Do not store above 25°C.

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

Do not use Gynest 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.

7 Further Information

The active substance in Gynest is estriol. Gynest contains 0.01% estriol.

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

What Gynest looks like and contents of the pack

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

The product licence is held by:
Marlborough Pharmaceuticals, 35A High Street,
Marlborough, Wiltshire, SN8 1LW

Gynest is made by:
PHARBIL Waltrop GmbH, Im Wirringen 12, D-45731,
Waltrop, Germany

For information in large print, tape, CD or Braille, telephone 01672 514187.

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