

Ovestin Cream

estriol 0.1% (1 mg per g)

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 further questions, please 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.

What is in this leaflet

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Cream Product description

This leaflet answers some common questions about Ovestin Cream.

It does not contain all of the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Ovestin Cream against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

(ovariectomy) before menopause, the decrease in estrogen production occurs very abruptly. The shortage of estrogens during menopause may cause the vaginal wall to become thin and dry. As a result, sexual intercourse may become painful and vaginal itching and infections may occur. Estrogen deficiency may also lead to symptoms like urinary incontinence and recurrent cystitis. Ovestin alleviates these symptoms after menopause. It may take several days or even weeks before you notice an improvement. You will only be prescribed Ovestin if your symptoms seriously hinder your daily life. In addition to the above uses, Ovestin Cream may also be prescribed to improve wound healing in postmenopausal women undergoing vaginal surgery or help assess cervical smears taken from postmenopausal women. After insertion into the vagina, estriol is slowly released and absorbed into the surrounding area and into the bloodstream.

A doctor's prescription is required to obtain this medicine.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or troubled breathing
- swelling of the face, lip, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- you have or have ever had breast cancer, or if you are suspected of having it.
- you have or if it is suspected that you have cancer which is sensitive to estrogens, such as cancer of the lining of the womb.
- you have any unexplained vaginal bleeding, which has not been evaluated by your doctor.
- you are pregnant or think you may be pregnant.
- you have excessive thickening of the lining of your womb (endometrial hyperplasia) that is not being treated.
- you have or have had a blood clot in a vein (thrombosis) such as in the legs (deep vein thrombosis) or the lungs (pulmonary embolism).
- you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency).
- you have or have had a disease caused by blood clots in the arteries such a heart attack, stroke or angina.
- you have or ever have had a liver disease and your liver function tests have not returned to normal.
- you have a rare blood problem called porphyria (an inherited or acquired disorder in the production of blood pigment).

What Ovestin Cream is used for

Ovestin Cream is a Hormone Replacement Therapy (HRT). It contains the female hormone estriol (an estrogen). Ovestin is used in postmenopausal women with at least 12 months since their last natural period. Ovestin is used for relief of symptoms occurring after menopause. During menopause, the amount of estrogens produced by a woman's body gradually drops. If the ovaries are removed surgically

Before using Ovestin Cream

When you must not use it

Do not use Ovestin Cream if

- you are allergic to estriol, or any of the ingredients listed at the end of this leaflet.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Ovestin Cream contains cetyl alcohol and stearyl alcohol. This may cause local skin reactions (e.g. contact dermatitis).

Take special care with Ovestin Cream

As well as benefits, Ovestin has some risks which you need to consider when you are deciding to start or continue treatment.

Medical check-ups

Before you start using Ovestin Cream, your doctor should ask about your own and your family's medical history. Your doctor may decide to examine your breasts and/or your abdomen, and may do an internal examination. You will also have periodic check-ups, especially examinations of the breasts. Your doctor will tell you how often these tests should be performed.

Once you have started using Ovestin Cream, you should see your doctor for regular check-ups (at least once every year). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to use Ovestin.

Certain conditions may be made worse by HRT. If you have or have had any of the following conditions and/or which were worse during pregnancy or with previous use of hormones tell your doctor who will monitor you closely:

- uterine (womb) fibroids
- endometriosis
- clots in the blood vessels (thrombosis, deep vein thrombosis, lung embolism) or an increased risk of developing this
- if anyone in your family has ever had an estrogen-dependent cancer, such as a close relative

- who has had breast cancer or cancer of the lining of the womb
- high blood pressure
- heart disease
- liver disorders
- kidney disorders
- diabetes
- gallstones
- migraine or (severe) headache
- systemic lupus erythematosus (SLE, an immune disorder affecting the skin and other organs)
- endometrial hyperplasia (thickening of the lining of the womb)
- epilepsy
- asthma
- otosclerosis (inherited deafness)
- fluid retention due to cardiac or kidney problems.

Tell your doctor if you notice any change in your condition while using Ovestin.

Reasons for immediately stopping Ovestin Cream:

- jaundice (your skin goes yellow)
- a sudden increase in blood pressure
- if you get migraine, or severe headaches, for the first time
- pregnancy.

HRT and cancer**Endometrial cancer**

Every woman is at a small risk of getting endometrial cancer (cancer of the lining of the womb), whether or not HRT is used. The risk of cancer of the lining of the womb increases with the duration of treatment.

Breakthrough bleeding or spotting may occur during the first few months of using Ovestin.

Tell your doctor if the bleeding or spotting:

- carries on for more than the first few months

- starts after you have been on Ovestin for a while
- carries on even after you have stopped using Ovestin.

Breast cancer

Women who have breast cancer, or have had breast cancer in the past, should not use Ovestin Cream.

Taking estrogen or estrogen-progestogen combined HRT or Ovestin for several years slightly increases the risk of breast cancer. The risk increases with the duration of use and returns to normal within about five years after stopping HRT. Women using combined HRT have a slightly greater risk of developing breast cancer than women using estrogen-only HRT.

It is not known whether Ovestin is associated with the same higher chance of having breast cancer diagnosed as other hormone replacement therapies.

Nevertheless, if you are concerned about the risk of breast cancer, discuss the risk compared to the benefits of treatment with your doctor.

Be sure to 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.

Ovarian Cancer

Ovarian cancer (cancer of the ovaries) is very rare, but it is a serious condition. It can be difficult to diagnose, because there are often no obvious signs of the disease.

Some studies have indicated 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 or Ovestin increase the risk in the same way.

Effects on your heart or circulation

Blood clots (thrombosis)

All women have a very small chance of having a blood clot in the veins of the leg, lungs or other parts of the body. Using some forms of HRT may slightly increase this small chance. It is unknown if Ovestin increases the risk in the same way.

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

You are more likely to have a blood clot if:

- you are older
- you are pregnant or have recently had a baby
- you have had one or more miscarriages
- you use estrogens
- you are seriously overweight
- you have had a blood clot before in the leg, lung or another organ
- blood clots run in your family
- you have any blood clotting problem that needs treatment with a medicine such as warfarin
- you have systemic lupus erythematosus (a disease of your immune system)
- you are unable to move for long periods, for example after a long illness or major operation
- you have cancer.

If any of these apply to you, you should talk to your doctor about whether you should use Ovestin Cream.

See a doctor as soon as possible and do not use any more Ovestin Cream if you get:

- painful swelling in your leg
- sudden chest pain
- difficulty breathing,

These may be signs of a blood clot.

Tell your doctor and your surgeon if you are to be hospitalized or undergo surgery.

You may need to stop using Ovestin about 4-6 weeks before the operation, to reduce the risk of a blood clot. Your doctors will tell you when you can start using Ovestin again.

Stroke

Recent research with one type of HRT (containing conjugated estrogen plus the progestogen MPA) has shown a slight increase in the risk of having a stroke.

If you have symptoms that might indicate that you have a stroke (such as unexplained migraine-type headaches, with or without disturbed vision), see a doctor as soon as possible. Do not use any more Ovestin until your doctor says you can.

Dementia

It is not known if there is an increased risk of dementia when using Ovestin.

Tell your doctor if you are pregnant.

Ovestin should not be used.

Tell your doctor if you are breast-feeding.

There is insufficient information on the use of Ovestin Cream during breast-feeding. Small amounts of the active estriol can be excreted in the breast milk and milk production could also be reduced.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Other medicines may interfere with the effects of estriol, or estriol may affect other medicines. This might lead to irregular bleeding. These include:

- anticoagulants (medicines to stop blood clots);
- corticosteroid hormones (includes many anti-asthmatic drugs);
- succinylcholine (medicine for muscle relaxation);
- theophyllines (medicine for asthma);
- medicines for epilepsy (such as barbiturates (phenobarbital),

hydantoin (phenytoin) and carbamazepine);

- medicines for fungal or bacterial infections (such as griseofulvin, rifamycins (rifampicin, rifabutin); troleandomycin);
- medicines for viral infections (eg. nevirapine, efavirenz, ritonavir, nelfinavir, ombitasvir, paritaprevir);
- herbal preparations containing St John's Wort (Hypericum Perforatum)

Tell your doctor if you have Hepatitis C and are taking the combination drug regimen

ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. Taking the combination of these drugs with some estrogen-containing products may cause increases in liver function blood test results (increase in ALT liver enzyme); the risk of this happening with Ovestin is currently unknown.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ovestin Cream.

How to use Ovestin Cream

How much to use

For vaginal complaints:

The usual dosage is 1 application daily during the first weeks. Later on the dose is gradually decreased to, for instance, 1 application twice a week. Each dose of cream contains 0.5 mg estriol. However your doctor may well prescribe different quantities for other conditions.

Your doctor may ask you to stop using Ovestin every 2 to 3 months for 4 weeks to check the need for further treatment.

For vulvo-vaginal complaints associated with menopause:

- initially one dose of cream per day for 3 weeks
- later you may only need one dose of cream twice a week.

Before surgery:

- one dose of cream daily beginning 2 weeks before the operation.

When having a Pap smear your doctor may recommend a daily application of cream for 7 days.

How to apply the cream

Use the applicator to apply the cream into the vagina.

It is a good idea to do this before retiring/going to sleep at night.

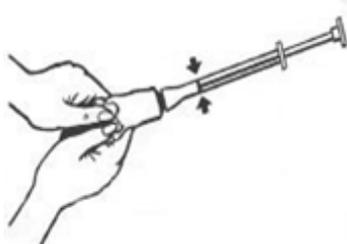
One application (applicator filled to the ring mark) contains 0.5 g of Ovestin cream, which contains 0.5 mg estriol.

Do not completely fill the whole applicator.

1. Remove cap from the tube, invert it, and use the sharp point to open the tube.
2. Screw the end of the applicator onto the tube. Make sure the plunger is fully inserted into the barrel.

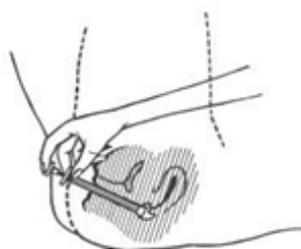


3. Squeeze the tube slowly to fill the applicator to the ring-mark (where the plunger stops).



4. Unscrew the applicator from the tube and put the cap on the tube.
5. To apply the cream, lie down, insert the applicator deep into the vagina.

6. Slowly push the plunger all the way in until the applicator is empty. Alternatively empty the applicator onto the end of a finger and insert finger into the vagina.



7. After use, pull the plunger out of the barrel beyond the point of resistance and wash both parts in warm, soapy water. Do not use detergents. Rinse well and dry afterwards.

Do NOT put the applicator in hot or boiling water.

8. The applicator can be re-assembled by fully inserting the plunger into the barrel beyond the point where resistance is felt.

Discard the applicator once the tube is empty.

If you forget to use it

If you forget a dose, use it as soon as you remember. But if you remember your missed dose at the time of your next dose, do not use an extra dose.

Do not use a double dose to make up for the missed dose.

This may increase the chance of you getting an unwanted side effect.

Then go back to using the cream as you would normally.

If you use too much (overdose)

If you may have used more Ovestin than you should, talk to a doctor or pharmacist.

If someone has swallowed some cream, there is no need for great concern. However, you should consult a doctor. Symptoms that may arise are nausea and vomiting. Vaginal bleeding in females may occur after a few days.

Side Effects of Ovestin Cream

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Ovestin Cream.

The medicine helps most women with menopausal symptoms, but it may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Dependent on dosage and sensitivity of the patient, Ovestin may sometimes cause side effects, such as:

- local irritation or itching
- burning feeling /sensation in or around the genital area
- swelling and increased tenderness of the breasts
- increased vaginal discharge
- discomfort when urinating (dysuria)
- nausea
- fluid retention in the tissues, usually marked by swollen ankles or feet.
- flu-like symptoms

In most patients these side effects will disappear after the first weeks of treatment. Tell your doctor if vaginal bleeding occurs or if any side effect becomes troublesome or persists.

Other side effects which may occur with HRT:

- benign and malignant hormone-dependent tumours such as endometrial cancer
- heart attack and stroke
- gall bladder disease
- skin problems such as rashes, discolouration or red patches on the skin
- various skin diseases with blisters and nodules or bleeding into the skin
- venous thromboembolism or deep leg or pelvic venous thrombosis and pulmonary embolism (see Before you use Ovestin Cream)
- using HRT for several years slightly increases the risk of breast cancer.

Tell your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

After Using Ovestin Cream

Storage

Keep your Ovestin Cream in a safe place out of the reach of children.

Keep your Ovestin Cream in the original package in a cool dry place where the temperature stays below 25°C.

Do not use after the expiry date stated on the tube and outer box.

Do not use if the product does not look quite right.

Product Description

What it looks like

Ovestin Cream is a homogeneous, smooth, white to nearly white mass of creamy consistency. Ovestin Cream is filled in a collapsible tube of 15 g. Each tube is packed together with a CE-marked applicator and a patient-instruction leaflet.

Do not use the product if the pack or cream is damaged or appears unusual.

Ingredients

Active ingredient:

estriol, 0.1%

Inactive ingredients:

- octyldodecanol
- cetyl palmitate
- glycerol
- cetyl alcohol
- stearyl alcohol
- polysorbate 60
- sorbitan monostearate
- lactic acid
- chlorohexidine hydrochloride
- sodium hydroxide

Sponsor Details

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Trading as Healthcare Logistics
Auckland, New Zealand
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Manufacturer of the Ovestin Applicator:

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