Ovestin Cream

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ovestin Cream?

Ovestin Cream contains the active ingredient estriol (a type of estrogen). Ovestin Cream is a local (vaginal) menopause hormone therapy (MHT) used for relief of symptoms occurring during and after menopause. The symptoms may include dryness and irritation in the vagina, and pain during sexual intercourse.

It's important to know that local (vaginal) treatment using Ovestin is different from taking systemic MHT such as tablets, using gels or wearing patches. At the recommended dose, the absorption of estriol from Ovestin Cream into the blood is low and does not produce any untoward systemic effect.

For more information, see Section 1. Why am I using Ovestin Cream? in the full CMI.

2. What should I know before I use Ovestin Cream?

Do not use if you have ever had an allergic reaction to Ovestin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Ovestin Cream? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ovestin Cream and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Ovestin Cream?

- Ovestin Cream is administered intravaginally by means of a calibrated applicator. Always use this medicine exactly as your doctor or pharmacist has told you.

More instructions can be found in Section 4. How do I use Ovestin Cream? in the full CMI.

5. What should I know while using Ovestin Cream?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Ovestin Cream. • If you become pregnant while using this medicine, stop using it and tell your doctor immediately. • Monitor your health and contact your doctor if you notice any changes. • Keep all of your doctor's appointments and go for regular check-ups.
Things you should not do	• Do not stop using this medicine suddenly without telling your doctor. • Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• No effects on the ability to drive and use machines have been observed.
Looking after your medicine	• Store Ovestin Cream in a cool dry place, out of direct light, where the temperature is below 30°C. • Keep Ovestin Cream in the original packaging, in a safe place, away from children.

For more information, see Section 5. What should I know while using Ovestin Cream? in the full CMI.

6. Are there any side effects?

As with any product that is to be applied to inner linings such as the vagina, Ovestin Cream may cause local irritation e.g. burning or itching in very sensitive people at the beginning of treatment. Other side effects may include swelling and increased tenderness of the breasts, increased vaginal discharge, nausea, fluid retention in the tissues, usually marked by swollen ankles or feet or flu-like symptoms. In general, these symptoms are temporary but may also be indicative of too high a dosage. If these symptoms persist, talk to your Doctor or Pharmacist.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Ovestin Cream

Active ingredient: *estriol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ovestin Cream. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ovestin Cream.**

Where to find information in this leaflet:

1. Why am I using Ovestin Cream?
2. What should I know before I use Ovestin Cream?
3. What if I am taking other medicines?
4. How do I use Ovestin Cream?
5. What should I know while using Ovestin Cream?
6. Are there any side effects?
7. Product details

1. Why am I using Ovestin Cream?

Ovestin Cream is a local, vaginal Menopause Hormone Therapy (MHT). It contains the active ingredient female hormone estriol (an estrogen). Absorption into the blood is low.

Ovestin Cream is used for relief of vulvo-vaginal symptoms caused by reduced estrogen levels during the climacteric.

Climacteric is the period of life starting from the decline in ovarian activity until after the end of ovarian function. This time includes peri-menopause, menopause and post-menopause. Throughout climacteric, the amount of estrogens produced by a woman's body gradually drops. If the ovaries are removed surgically (ovariectomy) before menopause, the decrease in estrogen production occurs very abruptly.

The shortage of estrogens during climacteric 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 helps restore the lining of the urogenital tissue and restore the normal microflora and the physiological pH in the vagina. As a result, it increases the resistance of these cells to infection and inflammation by reducing vaginal and urinary symptoms.

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. Absorption into the blood is low.

2. What should I know before I use Ovestin Cream?

Warnings

Do not use Ovestin Cream if:

- you are allergic to estriol, or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or troubled breathing
  - swelling of the face, lips, 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 anaphylactic reaction, angioedema or hypersensitivity to Ovestin
- 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 uterus
- you have any unexplained vaginal bleeding
- 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)

Check with your doctor if you:

- have any other medical conditions
- 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).

If you have or have had any of the following conditions, tell your doctor before starting Ovestin Cream:

- fibroids inside your uterus
- growth of uterus lining outside your uterus (endometriosis) or a history of excessive growth of the uterus lining (endometrial hyperplasia)
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)"
- increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- 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)
- epilepsy
- asthma
- otosclerosis (inherited deafness)
- fluid retention due to cardiac or kidney problems.

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, if necessary.

During treatment with Ovestin Cream, periodic check-ups are recommended of a frequency and nature adapted to the individual woman.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not use Ovestin if you are pregnant. Ovestin is for use in women who have reduced estrogen levels during and after menopause. If you become pregnant, stop using Ovestin and contact your doctor.

Do not breast-feed if you are using Ovestin. The active ingredient estriol passes into breast milk and there is a possibility that your baby may be affected.

MHT and cancer risk

The information describing the risk of cancer development whilst using Ovestin Cream is generalised from studies mainly using **oral** medicines in which the women take synthetic, animal derived and natural estrogens. In some studies estrogen was combined with progesterone.

Your risk of developing a cancer whilst using Ovestin cream should therefore be considered based on the special features of this medicine.

Ovestin Cream is applied topically rather than taken by mouth. The concentration of estriol entering the blood is consequently low.

Ovestin Cream contains the natural female hormone estriol rather than synthetic or animal derived estrogen. It does not contain progesterone.

If you remain concerned, discuss the benefits and potential risks of Ovestin treatment further with your doctor or pharmacist.

Endometrial cancer
Unlike other estrogens, estriol is short acting since it has only a short retention time in the nuclei of endometrial cells.

One epidemiological study has shown that long-term treatment with low doses of oral estriol, **but not** vaginal estriol, may increase the risk for endometrial cancer.

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 MHT 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 MHT. Women using combined MHT have a slightly greater risk of developing breast cancer than women using estrogen-only MHT. It is not known whether Ovestin is associated with the same higher chance of having breast cancer diagnosed as other hormone replacement therapies.

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. Some studies have indicated that taking systemic estrogen-only MHT for a long period of time (5-10 years) may increase the risk of ovarian cancer. It is not known whether Ovestin, a local vaginal treatment, has the same risk.

Effects of MHT on heart or circulation

Blood clot (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 MHT may slightly increase this small chance. It is unknown if Ovestin increases the risk in the same way as Ovestin was not part of the study.

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 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 pregnant or have recently had a baby
- you have had one or more miscarriages
- you use estrogens
- you are obese
- 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 (SLE)
- you are unable to move for long periods, for example after a long illness or major operation
- you have cancer.

Stroke

For women aged 50–59 who aren't using MHT, about 3 in 1,000 (0.3%) are expected to have a stroke over a 5-year period. Research on one specific type of systemic MHT (containing ***conjugated estrogen*** plus MPA - medroxyprogesterone acetate) shows it may add a very small extra risk of about 1 in 1,000 (0.1%).

For women aged 60–69 who aren't using MHT, about 11 in 1,000 (1.1%) are expected to have a stroke over a 5 year period. With that same type of systemic MHT as above, the risk increases by about 4 more in 1,000 (0.4%)

Ovestin Cream **does not** contain conjugated estrogen plus the progestogen.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Ovestin Cream and affect how it works. 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), hydantoins (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.

4. How do I use Ovestin Cream?

How much to use

For vulvo-vaginal complaints associated with menopause:

- Follow the instructions provided and use Ovestin Cream until your doctor tells you to stop.
  - Initially one dose of cream per day for 3 weeks
  - As maintenance dosage one dose of cream twice a week is recommended.

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

Before vaginal surgery:

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

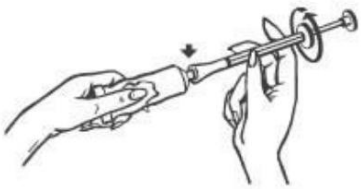
When having a Pap smear, your doctor may recommend a daily application of cream for 7 days.

How to apply Ovestin Cream

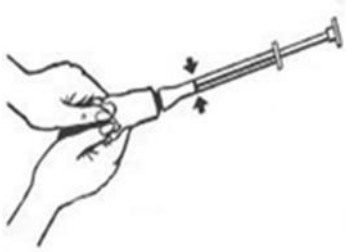
- Ovestin Cream is intended for intravaginal administration by means of a calibrated applicator included in the pack.
- Always use this medicine exactly as your doctor or pharmacist has told you.
- One application (applicator filled to the ring mark) contains 0.5 g of Ovestin cream, which contains 0.5 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.

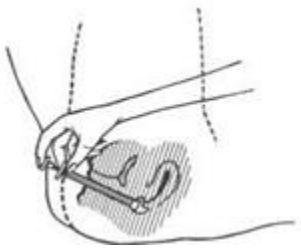
2. Screw the end of the applicator onto the tube. Make sure the plunger is fully inserted into the barrel.



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, and 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 Ovestin Cream

If you miss your dose at the usual time, use it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

If you use too much Ovestin Cream

If you think that you have used too much Ovestin Cream, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ovestin Cream?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Ovestin.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using Ovestin.

If you become pregnant while you are using Ovestin, stop using it and tell your doctor immediately.

If you are hospitalised or undergo surgery, tell your doctor and your surgeon that you are using Ovestin. 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.

Conduct monthly self-examination of your breasts. Your doctor or nurse can show you how to check your breasts properly. If you notice any changes to your breasts, see your doctor.

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.

Thinks you should not do

- Do not use Ovestin to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine without checking with your doctor.

Driving or using machines

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

Looking after your medicine

Keep your Ovestin Cream in the original package in a cool dry place where the temperature stays below 30°C, away from moisture, heat or sunlight; do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Do not use this medicine if it does not look quite right.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Dependent on dosage and sensitivity of the patient, Ovestin may cause side effects as shown below, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• irritation or itching of skin in or around vagina • 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	**Speak to your doctor if these side effects worry you.**

Serious side effects

Serious side effects	What to do
• signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing • yellowing of your skin or the whites of your eyes (jaundice) • a sudden increase in blood pressure • migraine or severe headaches • thrombosis (red, painful or swollen leg, difficulty breathing, chest pain, headache or pain elsewhere in your body, dizziness, fainting, disturbances in vision, swollen ankles.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ovestin Cream contains

Active ingredient (main ingredient)	Estriol 0.1% (1 mg per g)
Other ingredients (inactive ingredients)	• octyldodecanol • cetyl esters wax • glycerol • cetyl alcohol • stearyl alcohol • polysorbate 60 • sorbitan monostearate • lactic acid • chlorhexidine hydrochloride • sodium hydroxide • purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Ovestin Cream 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 (AUST R 14515).

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

Who distributes Ovestin Cream

Aspen Pharmacare Australia Pty Ltd
St Leonards, NSW 2065
Australia

Manufacturer of the Ovestin applicator:

Aspen Bad Oldesloe GmbH
Industriestrasse 32-36
23843 Bad Oldesloe
Schleswig-Holstein
Germany

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