

Ovestin Ovula

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 Ovula?

Ovestin Ovula contains the active ingredient estriol. Ovestin Ovula is used for relief of symptoms occurring after menopause.

For more information, see Section [1. Why am I using Ovestin Ovula?](#) in the full CMI.

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

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 Ovula?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ovestin Ovula 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 Ovula?

- Ovestin Ovula is administered intravaginally. 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 Ovula?](#) in the full CMI.

5. What should I know while using Ovestin Ovula?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Ovestin Ovula.• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• No effects on the ability to drive and use machines have been observed.
Looking after your medicine	<ul style="list-style-type: none">• Store Ovestin Ovula in a cool dry place, out of direct light, where the temperature is below 30°C.• Avoid excessive heat: the pessary will melt at temperatures above 32°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Side effects include local irritation or itching of skin in or around vagina, 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.

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 Ovula

Active ingredient: *estriol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ovestin Ovula. **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 Ovula.**

Where to find information in this leaflet:

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

1. Why am I using Ovestin Ovula?

Ovestin Ovula is a Hormone Replacement Therapy (HRT). It contains the active ingredient female hormone estriol (an estrogen).

Ovestin is used for relief of symptoms occurring after menopause. It is used in postmenopausal women with at least 12 months since their last natural period.

During menopause, 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. In many cases the decrease in estrogen production leads to well-known menopausal complaints such as hot flushes and night sweating. The shortage of estrogens may cause the vaginal wall to become thin and dry. As a result sexual intercourse 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 Ovula may also be prescribed to treat certain forms of infertility, improve wound healing in postmenopausal women undergoing vaginal surgery or help assess cervical smears taken from postmenopausal women.

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

Warnings

Do not use Ovestin Ovula 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 womb.
- 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 as 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.

Certain conditions may be made worse by HRT. If you have or have had any of the following conditions, tell your doctor before starting Ovestin Ovula as these may return or become worse during treatment with this medicine:

- 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 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 Ovula, 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/breast screening. Your doctor will tell you how often these tests should be performed.

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 postmenopausal women only. 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.

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 Ovula.

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 of HRT 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 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 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 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 (SLE)
- you are unable to move for long periods, for example after a long illness or major operation
- you have cancer.

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.

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 Ovula 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 you 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 Ovula.

4. How do I use Ovestin Ovula?

How much to use

For vaginal complaints:

- the usual dosage is one pessary daily during the first weeks. Later on the dose is gradually decreased to, for instance, one pessary twice a week. For other conditions, a different dosage may be prescribed.
- 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 pessary per day for 3 weeks
- Later you may only need one pessary twice a week.

Before vaginal surgery:

- One pessary daily beginning 2 weeks before the operation

When having a Pap smear your doctor may recommend a daily insertion of 1 pessary for 7 days.

How to insert a pessary

The pessary should be inserted into the vagina before retiring at night.

You may need to moisten your first few pessaries with water before insertion if you are particularly dry and insertion feels uncomfortable.

- Remove one pessary from its wrapper.
- Either using a squatting position or lying on your back or side, insert the pessary deeply into the vagina.

If you forget to use Ovestin Ovula

If you miss your dose, use it as soon as you remember.

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

Do not use 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 Ovula

If you think you may have used more Ovestin than you should, 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 Ovula?

Things you should do

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

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

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

If you are to be 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 Ovula in the original package in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; do not store it:

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

Avoid excessive heat: the pessary will melt at temperatures above 32°C.

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
<ul style="list-style-type: none"> • local irritation or itching of skin or around vagina. • swelling and increased tenderness of the breasts • increased vaginal discharge • nausea 	<p>Speak to your doctor if these side effects worry you.</p>

<ul style="list-style-type: none"> • fluid retention in the tissues, usually marked by swollen ankles or feet • flu-like symptoms. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>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.</p>

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 Ovula contains

Active ingredient (main ingredient)	Estriol, 0.5 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • hard fat • cetomacrogol 1000 • glyceryl ricinoleate

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

What Ovestin Ovula looks like

Packs contain 3 blister strips, each strip contains 5 pessaries. Ovestin Ovula are white to light cream coloured, torpedo shaped pessaries (AUST R 35632).

Do not use the product if the blister pack or pessaries are damaged or appear unusual.

Who distributes Ovestin Ovula

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards, NSW 2065
Australia

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