

Ovestin[®] Tablets

Oestriol 2 mg

What is in this leaflet

Please read this leaflet carefully before you start using Ovestin tablets.

This leaflet answers some common questions about Ovestin tablets. It does not contain all the available information. 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 tablets 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 with the medicine. You may need to read it again.

What Ovestin tablets are used for

Ovestin tablets is a Hormone Replacement Therapy (HRT). It contains the female hormone oestriol (an oestrogen). 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 oestrogens produced by a woman's body gradually drops. If the ovaries are removed surgically (ovariectomy) before menopause, the decrease in oestrogen production occurs very abruptly. In many cases the decrease in oestrogen production leads to well-known menopausal complaints such as hot flushes and night sweating. The shortage of oestrogens may cause the vaginal wall to become thin and dry. As a result sexual intercourse become painful and vaginal itching and infections may occur. Oestrogen 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 Tablets 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.

Your doctor may have prescribed Ovestin tablets for another reason.

Ask your doctor if you have any questions about why Ovestin tablets have been prescribed for you.

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

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

Before you use Ovestin tablets

When you must not use it

Do not use Ovestin tablets if:

- you have or have ever had breast cancer, or if you are suspected of having it.
- you are pregnant or think you may be pregnant
- you have or if it is suspected that you have cancer which is sensitive to oestrogens, such as cancer of the lining of the womb
- you have any unexplained vaginal bleeding, which has not been evaluated by your doctor
- 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 (thrombosis in the veins of 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 had an allergic reaction to oestriol, or any of the other ingredients of Ovestin
- you have a rare blood problem called porphyria (an inherited or acquired disorder in the production of blood pigment).

Do not use Ovestin if you have an allergy to:

- any medicine containing oestriol
- 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.

If you are not sure whether you should start using Ovestin tablets, talk to your doctor.

Before you start to use it

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

Take special care with Ovestin Tablets

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

Medical check-ups

Before you start taking Ovestin, 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 taking Ovestin Tablets, 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 take Ovestin

Certain conditions may be made worse by hormone replacement therapy (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 oestrogen-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)

If you have not told your doctor about any of the above, tell them before you start using Ovestin tablets.

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

Reasons for immediately stopping Ovestin Tablets:

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

Effects on your risk of developing 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 taking 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 taking Ovestin.

Breast cancer

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

Taking oestrogen or oestrogen- 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 oestrogen-only HRT.

It is not known whether Ovestin is associated with the same higher risk of breast cancer as other HRT.

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 oestrogen-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 one or more miscarriages
- you use oestrogens
- 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 Tablets.

If you get a blood clot while you are using Ovestin Tablets you should stop taking it immediately and contact your doctor.

See a doctor as soon as possible 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 taking 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.

Heart disease

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

Ovestin will not help to prevent heart disease.

Studies with one type of HRT (containing conjugated oestrogen plus the progestogen MPA) have shown that women may be slightly more likely to get heart disease during the first year of taking the medication. For other types of HRT, the risk is likely to be similar, although this is not yet certain.

If you have symptoms that might indicate that you have a heart disease (such as pain in your chest that spreads to your arm or neck), see a doctor as soon as possible. Do not take any more HRT until your doctor says you can.

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 take any more Ovestin until your doctor says you can.

Dementia

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Ovestin tablets.

Some medicines may interfere with Ovestin tablets. 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 (nevirapine, efavirenz, ritonavir, nelfinavir)
- herbal preparations containing St John's wort (*Hypericum Perforatum*)

These medicines may be affected by Ovestin tablets, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Ovestin tablets.

Tell your doctor if you are pregnant.

Ovestin Tablets should not be taken.

Tell your doctor if you are breast-feeding.

Small amounts of the active oestriol can be excreted in the breast milk and milk production could also be reduced.

Tell your doctor if you react badly to lactose or milk before you start taking Ovestin.

Ovestin Tablets contain lactose.

How to use Ovestin tablets

How much to take

Your doctor will usually prescribe this product as a daily dosage of up to 4-8 mg daily. This dose is usually given in the first 5-7 days and can then be reduced to a maintenance level of for example 1-2 mg daily in the following 1-3 weeks depending on what your doctor thinks about your response to the treatment.

The score line is there to help you break the tablet if you have difficulty swallowing it whole.

When to take it

Ovestin Tablets should be taken orally with water. You should take your tablets at about the same time each day.

How long to take it

If you require treatment for long periods then your doctor will review your need to continue at least every 6 months. You would not normally take the tablets for more than 12 months.

If you forget to take it

If you forget to take a tablet, take it as soon as you remember, unless you are more than 12 hours late. In this case, 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 that you missed.

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

While you are using Ovestin tablets

Things you must do

If you become pregnant while using Ovestin Tablets, tell your doctor immediately.

It should not be used while you are pregnant.

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.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Ovestin tablets.

Things you must not do

Do not give Ovestin Tablets to anyone else, even if they have the same condition as you.

Do not use Ovestin Tablets to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too many Ovestin tablets.

Do this even if there are no signs of discomfort or poisoning.

Overdose may cause nausea and vomiting. Vaginal bleeding in females may also occur after a few days.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

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.

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

- swelling and increased tenderness of the breasts
- vaginal bleeding
- increased vaginal discharge
- 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 take Ovestin Tablets)
- using HRT for several years slightly increases the risk of breast cancer.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Ovestin tablets

Storage

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

Keep your Ovestin Tablets in the original package in a cool dry place where the temperature stays below 30°C.

Do not take after the expiry date stated on the blister and outer box.

Disposal

Return to a pharmacy any unused medicine, and any medicine past its expiry date as shown on the dispensing label or on the packaging. Return also any medicine which no longer looks right.

Product description

What it looks like

Ovetin tablet packs contain one blister strip of 30 white round flat, scored tablets with bevelled edges. The tablets are marked 'DG' above '8' on one side.

Ingredients

Active ingredient:

- oestriol 2 mg

Inactive ingredients:

- potato starch
- povidone
- silica colloidal anhydrous
- magnesium stearate
- lactose monohydrate

Sponsor Details

Ovestin tablets are supplied in New Zealand by:

Pharmacy Retailing (NZ) Pty Ltd
Trading as Healthcare Logistics
Auckland,
NEW ZEALAND

Ph 09 9702760

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