

## Ovestin® tablets

estriol 1 mg

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Ovestin tablets.

It does not contain all 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 taking Ovestin Tablets against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist**

**Keep this leaflet.**

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 estriol (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.

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.

#### Before you take it

##### *When you must not take it*

##### **Do not take 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 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 had an allergic reaction to estriol, 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 take Ovestin if you have an allergy to:**

- any medicine containing estriol
- 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.

##### *Before you start to take 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)

**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.

Evidence from studies suggests an increased risk in women taking oestrogen-only or combined oestrogen-progestogen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping.

Some other studies, including the Women's Health Initiative (WHI) trial, suggest that use of combined HRTs may be associated with a similar risk. It is not yet known whether Ovestin increases 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 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 influence the effects of estriol, or estriol may affect other medicines. 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*)

**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 estriol 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 take it

### 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 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 only there to help you break the tablet if you have difficulty swallowing it whole.

### 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.

### When to take it

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

### 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.

### If you take too much (overdose)

**If you think you or anyone else may have taken too much contact your doctor for advice.**

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

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## While you are taking it

### 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, remind your doctor or pharmacist that you are taking Ovestin Tablets.**

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Ovestin Tablets.**

### Things you must not do

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

**Do not give Ovestin Tablets to anyone else, even if their symptoms seem to be the same as yours.**

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## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ovestin Tablets.**

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 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.

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

Other side effects not listed above may also occur in some people.

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**After taking it**

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*Storage*

**Keep this medicine 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.**

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**Product description**

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*What it looks like*

Packs contain one blister strip of 30 white round flat, scored tablets with bevelled edges. The tablets are marked 'DG' above '7' on one side.

*Ingredients*

Ovestin tablets contain 1 mg of estriol as the active ingredient.

They also contain:

- amylopectin
- magnesium stearate
- potato starch
- lactose monohydrate.

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

*Distributor*

Aspen Pharmacare Pty Ltd  
34 – 36 Chandos St  
St Leonards  
NSW 2065  
Australia  
AUST R 14514

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