

# Ovestin Cream

Oestriol 0.1% (1mg per g)

Before this medicine is inserted, please read this page carefully. Below on this page you will find more information about Ovestin Cream, as well as some general advice on using medicines. If you have any questions or you would like further information, please ask your doctor or pharmacist.

#### General advice

1. This medicine has been prescribed only for your current medical problem. It should not be used for other medical conditions.
2. Never give your medicine to anyone else and do not use medicines meant for other people.
3. Tell every doctor treating you what medicines you are taking. Always carry a medical information card stating which medicines you are using. This can be very important if for example you are involved in an accident.
4. Return unused medicines to your pharmacy for disposal.
5. Make sure that other people who live with you or who look after you read this information.

## What is in this leaflet

### What Ovestin Cream is used for

### Before using Ovestin Cream

### How to use Ovestin Cream

### Side effects of Ovestin Cream

### After using Ovestin 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.

## What Ovestin Cream is used for

Ovestin Cream is used in Hormone Replacement Therapy (HRT) in women. It contains oestriol. Oestriol is one of the female hormones, called oestrogens, that your body makes. During and after the change of life (menopause) the oestrogen production by your body decreases. This decrease may lead to hot flushes, vaginal irritation, recurrent urinary tract infections and urinary incontinence. Ovestin Cream can be prescribed for the loss of oestrogen production by your body. After insertion into the vagina, oestriol is slowly released and absorbed into the surrounding area and even 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.

## Before using Ovestin Cream

### **When you must not use it**

Ovestin Cream may not be suitable for you if you suffer or have suffered from certain medical conditions.

### Do not use Ovestin Cream if:

- you have or have had breast cancer, or if breast cancer is suspected
- you are pregnant or think you may be pregnant
- you have or if it is suspected that you have an oestrogen-dependent tumour, such as cancer of the lining of the womb
- you have abnormal vaginal bleeding, which has not been evaluated by your doctor
- you have abnormal growth of the lining of your womb (endometrial hyperplasia)
- you have or have had a blood circulation disorder such as blood clots (in the veins of the legs or the lungs)
- you have a blood clotting disorder (thrombophilic 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 angina pectoris, stroke or a heart attack
- you have or have had liver disease as long as the function of the liver has not returned to normal
- you have had an allergic reaction to oestriol, or any of the other ingredients of Ovestin
- you have porphyria (an inherited or acquired disorder in the production of blood pigment)

**Do not use Ovestin Cream 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

**Before you start to use it**

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

**Important information about some of the ingredients of Ovestin Cream**

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

**You must also tell your doctor if you have or have ever had:**

- disease or symptoms that may be aggravated during pregnancy or previous use of hormones such as severe itching, skin rash (herpes gestationis), or chloasma (brown, blotchy spots on skin exposed to the sun that may appear during pregnancy); fibrocystic mastopathy,
- metabolic bone disease

**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 taking HRT, 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 get periodic check-ups, especially examinations of the breasts. Your doctor will tell you how often these tests should be performed.

Once you've started on HRT, you should see your doctor for regular check-ups (at least once a year). At these checkups, your doctor may discuss with you the benefits and risks of continuing to use Ovestin.

HRT can sometimes cause fluid retention. If you have a vaginal infection, your doctor will also prescribe a medicine to treat the infection.

Certain conditions may be made worse by HRT. If you have or have had any of the following conditions or deteriorated 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 Cream**

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

**Effects on your risk of developing cancer**

**Endometrial cancer**

Every woman has a small risk of developing endometrial cancer (cancer of the lining of the womb), whether or not she takes HRT.

To prevent endometrial stimulation the maximum dose should not be exceeded nor should the maximum dose be used for longer than several weeks.

If you get breakthrough bleeding or spotting, it's usually nothing to worry about, especially during the first few months of taking HRT.

But if the bleeding or spotting:

- carries on for more than the first few months
- starts after you've been on HRT for a while
- carries on even after you have stopped taking HRT

Make an appointment to see your doctor to determine if these signs require further evaluation.

### **Breast cancer**

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

Taking oestrogen or oestrogen-progestogen combined HRT for several years slightly increases the risk of breast cancer. The risk increases with the duration of HRT 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. 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 serious. 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**

### **Heart disease (coronary artery disease)**

HRT 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 HRT.

HRT 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 get:

- a pain in your chest that spreads to your arm or neck

see a doctor as soon as possible and do not use any more Ovestin Cream until your doctor says you can. This pain could be a sign of heart disease.

### **Stroke**

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

Looking at women in their 50's who are not taking HRT – on average, over a 5-year period, 3 in 1000 would be expected to have a stroke. For women in their 50's who are taking HRT, the figure would be 4 in 1000.

Looking at women in their 60's who are not taking HRT – on average, over a 5-year period, 11 in 1000 would be expected to have a stroke. For women in their 60's who are taking HRT, the figure would be 15 in 1000.

It is not yet known whether other kinds of HRT increase the risk in the same way.

If you get:

- unexplained migraine-type headaches, with or without disturbed vision

see a doctor as soon as possible and do not use any more Ovestin Cream until your doctor says you can. These headaches may be an early warning sign of a stroke.

### **Blood clots (thrombosis)**

HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis or DVT), especially during the first year of taking it. 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, or PE.

DVT and PE are examples of a condition called venous thromboembolism, or VTE.

You are more likely to get a blood clot:

- if you are older
- if you are pregnant or have recently had a baby
- if you have had one or more miscarriages
- if you use oestrogens
- if you are seriously overweight
- if you have had a blood clot before in the leg, lung or another organ
- if any of your close family have had blood clots
- if you have any blood clotting problem that needs treatment with a medicine such as warfarin
- if you are off your feet for a long time because of major surgery, injury or illness
- if you have a rare

condition called systemic lupus erythematosus (a disease of your immune system)

- if you have cancer

If any of these things apply to you, talk to your doctor to see if you should use Ovestin Cream.

Looking at women in their 50's who are not taking HRT – on average, over a 5-year period, 3 in 1000 would be expected to get a blood clot in a vein. For women in their 50's who are taking HRT, the figure would be 7 in 1000.

Looking at women in their 60's who are not taking HRT – on average, over a 5-year period, 8 in 1000 would be expected to get a blood clot. For women in their 60's who are taking HRT, the figure would be 17 in 1000.

If you get:

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

see a doctor as soon as possible and do not use any more Ovestin Cream until your doctor says you can. These may be signs of a blood clot.

If you are going to have surgery, make sure your doctor knows about it. You may need to stop taking HRT about 4 to 6 weeks before the operation, to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.

**If you are pregnant**, or think that you may be pregnant, Ovestin Cream should not be used.

**If you are breast-feeding**, tell your doctor before Ovestin Cream is used.

### **Dementia**

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

### **Taking other medicines**

Other medicines may influence the effects of Ovestin, or Ovestin may affect other medicines. You must tell your doctor or pharmacist if you are taking (or intend to take) other medicines such as:

- 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, hydantoins and carbamazepine);
- medicines for fungal or bacterial infections (such as griseofulvin, rifamycins, troleandomycin);
- medicines for viral infections (nevirapine, efavirenz, ritonavir, nelfinavir)
- medicines to control blood sugar levels (for diabetes);
- herbal preparations containing St John's Wort (*Hypericum Perforatum*)

If you wish to discuss any aspect of the product further, you may speak with your doctor or pharmacist.

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## **How to use Ovestin Cream**

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### **How much to use**

Ovestin Cream is intended to be put in the vagina. Each dose of cream contains 0.5mg oestriol. Your doctor will usually prescribe this product in the doses listed below. However, your doctor may well prescribe different quantities for certain patients.

-For vulvo-vaginal complaints associated with menopause:

initially one dose of cream per day during the first 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.
- then one dose twice a week for 2 weeks after surgery.

-When having a Pap smear your doctor may recommend one application of cream on alternate days for 7 days.

Your doctor may ask you to stop using Ovestin every 2 to 3 months for 4 weeks to check the need for further treatment. If an unexpected vaginal bleed occurs, you should contact your doctor.

### **How to use it**

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 0.5g of Ovestin Cream, which contains 0.5 mg oestriol.

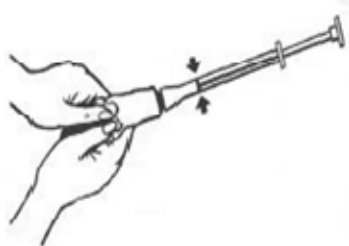
### **Do not completely fill the whole applicator.**

Each tube of Ovestin Cream contains enough for 30 doses.

1. Remove the 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.

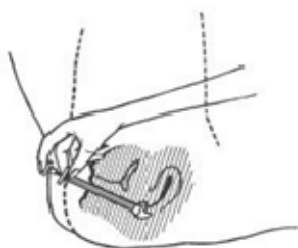


3. Squeeze the tube to fill the applicator to the ring-mark (where the plunger stops).



4. Unscrew the applicator from the tube and replace the cap.

5. To apply the cream, lie down, insert the applicator deep into the vagina and slowly push the plunger all the way in, until the applicator is empty.



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

**Do NOT put the applicator in hot or boiling water.**

#### ***If you forget to use it***

If you forget to administer a dose, administer it as soon as you remember, unless you notice the missed dose at the day of your next dose. If you notice the missed dose at the day of your next dose, do not administer the missed dose, and just carry on with the next dose as normal.

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

#### ***If you use more Ovestin Cream than you should***

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

#### ***What to do if someone has***

#### ***swallowed some cream accidentally***

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; in females vaginal bleeding may occur after a few days.

Telephone your doctor or Poisons Information Centre (in New Zealand, National Poisons Centre, telephone 0800 POISON or 0800 764 766) or go to the accident and emergency centre at your nearest hospital immediately if you or anyone else swallows Ovestin Cream.

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### **Side Effects of Ovestin Cream**

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Like all medicines, Ovestin can have side effects.

Dependent on dosage and your sensitivity, Ovestin may sometimes cause side effects, such as:

- local irritation or itching
- swelling and increased tenderness of the breasts

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 continues.

Other side-effects which may occur with HRT:

- benign and malignant hormone-dependent tumours such as breast cancer and endometrial cancer
- venous thromboembolism or deep leg or pelvic venous thrombosis and pulmonary embolism (see "**Before using Ovestin Cream**")
- 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
- using HRT for several years slightly increases the risk of breast cancer
- dementia (decline in mental function marked by memory loss)

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

Seek advice from your doctor or pharmacist before using other medications to deal with any side-effects you may be experiencing.

See the section "**Before using Ovestin Cream**".

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### **After Using Ovestin Cream**

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#### ***Storage***

Keep in a safe place out of reach of children.

The shelf life of Ovestin Cream is 3 years when stored below 30°C. Check if there are special storage conditions given on the box.

The expiry date (sometimes written as "exp") is printed on the pack – do not use after this date.

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

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### **Product Description**

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#### ***What it looks like***

Ovestin Cream is a white water emulsion which also contains octyldodecanol, cetyl palmitate, glycerol, cetyl alcohol, stearyl alcohol, polysorbate 60, sorbitan

monostearate, lactic acid,  
chlorohexidine hydrochloride  
and sodium hydroxide.

**The box** contains a tube with  
15g cream (1mg/g of oestriol),  
an applicator and a patient  
instruction leaflet.

**Sponsor:**

Merck Sharp & Dohme (NZ)  
Ltd  
PO Box 99-851  
Newmarket  
Auckland 1149

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