

# Ovestin Cream

Oestriol 0.1% (1mg per g)

## Consumer Medicine Information

### What is in this leaflet

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 wish to read it again

### What Ovestin Cream is used for

Ovestin Cream contains the natural female hormone oestriol. During and after the menopause the production of oestrogen by the 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 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**

#### **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 tumor, 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 or have had a heart condition such as angina pectoris 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.**

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

#### **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 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. You will also have periodic check-ups, especially examinations of the breasts.

Once you have started using Ovestin Cream, you should see your doctor for regular check-ups (at least every 6 months). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to use Ovestin.

Certain conditions may be made worse by hormone replacement therapy (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
- \* a history of clots in the blood vessels
- \* 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
- \* liver disorders
- \* diabetes
- \* gallstones
- \* migraine or (severe) headache
- \* systemic lupus erythematosus (SLE, an immune disorder affecting the skin and other organs)
- \* a history of 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)
- \* 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 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 oestrogen or oestrogen-progestagen 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 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 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 seriously overweight
- \* you have had a blood clot before
- \* blood clots run in your family
- \* 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

If any of these apply to you, you should talk to your doctor about whether you should use Ovestin Cream.

**See a doctor as soon as possible and do not use any more Ovestin Cream 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 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.

### **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.

**Tell your doctor if you are pregnant.**

Ovestin should not be used.

**Tell your doctor if you are breast-feeding.**

There is insufficient information on the use of Ovestin Cream during breast-feeding. Small amounts of the active oestriol can be excreted in the breast milk and milk production could also be reduced.

### **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 oestriol, or oestriol 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, hydantoins and carbamazepine)
- \* medicines for fungal or bacterial infections (such as griseofulvin, rifamycins; troleandomycin)
- \* medicines for viral infections (nevirapine, efavirenz, ritonavir, nelfinavir)
- \* herbal preparations containing St Johns wort (*Hypericum Perforatum*)

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## **How to use Ovestin Cream**

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### **How much to use**

For vaginal complaints the usual dosage is 1 application daily during the first weeks. Later on the dose is gradually decreased to, for instance, 1 application twice a week. Each dose of cream contains 0.5 mg oestriol. However your doctor may well prescribe different quantities for other conditions.

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 the menopause:

- \* initially one dose of cream per day for 3 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.

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

### **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 0.5 mg of Ovestin cream, which contains 0.5 mg oestriol.

**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.
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.

After use, pull the plunger out of the barrel and 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 a dose, use it as soon as you remember. But if you remember your missed dose at the time of your next dose, do not use an extra dose.

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

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

Then go back to using the cream as you would normally.

### ***If you use too much (overdose)***

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

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. Vaginal bleeding in females may occur after a few days.

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## **Side Effects of Ovestin Cream**

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

The medicine helps most women with menopausal symptoms, but it may have unwanted side effects in a few people. All medicines can 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 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 persists.

Other side effects which may occur with HRT:

- \* benign and malignant hormone-dependent tumors such as endometrial cancer
- \* heart attack and stroke
- \* gall bladder disease
- \* skin problems such as rashes, discolouration or red patches on the skin

- \* Venous thromboembolism or deep leg or pelvic venous thrombosis and pulmonary embolism (see Before you use Ovestin Cream)
- \* 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.**

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## **After Using Ovestin Cream**

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### ***Storage***

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

**Keep your Ovestin Cream in the original package in a cool dry place where the temperature stays below 30 degrees C.**

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

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

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

### ***Ingredients***

Ovestin Cream contains 0.5 mg of oestriol in each 0.5 mg dose as the active ingredient.

It also contains:

- \* octyldodecanol
- \* cetyl esters wax

- \* glycerol
- \* cetyl alcohol
- \* stearyl alcohol
- \* polysorbate 60
- \* sorbitan monostearate
- \* lactic acid
- \* chlorohexidine hydrochloride
- \* sodium hydroxide

### ***Distributor***

Schering-Plough Pty Limited  
Level 4, 66 Waterloo Road,  
North Ryde NSW 2113  
Australia

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