

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Ovestin® 1mg vaginal cream**  
**(estriol)**

The full name of your medicine is Ovestin 1mg vaginal cream. It is called Ovestin throughout the remainder of this leaflet.

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

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**1. What Ovestin is and what it is used for**

The name of your medicine is Ovestin 1 mg cream. Ovestin contains a medicine called estriol. Ovestin belongs to a group of medicines called Hormone Replacement Therapy (HRT).

It is used to relieve menopausal symptoms in the vagina such as dryness or irritation. In medical terms this is known as 'vaginal atrophy'. It is caused by a drop in the levels of oestrogen in your body. This happens naturally after the menopause.

This medicine works by replacing the oestrogen which is normally produced in the ovaries of women. It is inserted into your vagina, so the hormone is released where it is needed. This may relieve discomfort in the vagina.

When women get older the ovaries gradually produce less oestrogen.

- This happens at the menopause (usually around the age of 50).
- If the ovaries are removed before the menopause, oestrogen production stops very suddenly.

Shortage of oestrogens may cause the vaginal wall to become thin and dry. So sexual intercourse may become painful and you may get vaginal infections. These problems can be relieved by using medicines like this medicine which contain oestrogen. It may take several days or weeks before you notice an improvement.

This medicine is used:

- Before or after vaginal surgery to help wound healing.

**2. Before you use Ovestin**

**Medical history and regular check-ups:**

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on this medicine you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with this medicine.

Go for regular breast screening, as recommended by your doctor.

**Do not use this medicine:**

If any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before using this medicine,

Do not use this medicine:

- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you have cancer **which is sensitive to estrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any **unexplained vaginal bleeding**
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**
- If you have or ever have had a **liver disease** and your liver function tests have not returned to normal
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited)
- If you are **allergic** (hypersensitive) to estriol or any of the other ingredients of this medicine (listed in section 6 Contents of the pack and further information)

If any of the above conditions appear for the first time while using this medicine, stop taking it at once and consult your doctor immediately.

**Warnings and precautions**

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with this medicine. If so, you should see your doctor more often for check-ups:

- 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
- a liver disorder, such as a benign liver tumor
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- fluid retention due to cardiac or kidney problems
- hereditary and acquired angioedema

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 oestrogen-containing products may cause increases in liver function blood test results (increase in ALT liver enzyme); the risk of this happening with this medicine is currently unknown. This medicine contains cetyl alcohol and stearyl alcohol. This may cause local skin reactions (e.g. contact dermatitis).

**Stop using this medicine and see a doctor immediately**

If you notice any of the following when taking HRT:

- any of the conditions mentioned in the 'DO NOT take this medicine' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs
  - sudden chest pain
  - difficulty in breathing

For more information, see 'Blood clots in a vein (thrombosis)'.

**Note:** This medicine is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

**HRT and cancer**

**Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)**

Taking oestrogen-only HRT tablets for a long time can increase the risk of developing cancer of the womb lining (the endometrium).

It is uncertain whether there is a similar risk with this medicine if used for repeated or long term (more than one year) treatments. However, this medicine has been shown to have very low absorption into the blood, therefore the addition of a progestagen is not necessary.

If you get bleeding or spotting, it's usually nothing to worry about, but you should make an appointment to see your doctor. It could be a sign that your endometrium has become thicker.

*The following risks apply to hormone replacement therapy (HRT) medicines which circulate in the blood. However this medicine is for local treatment in the vagina and the absorption into the blood is very low. It is less likely that the conditions mentioned below will get worse or come back during treatment with Ovestin, but you should see your doctor if you are concerned.*

**Breast cancer**

Evidence suggests that using this medicine does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if this medicine can be safely used in women who had breast cancer in the past.

**Regularly check your breasts. See your doctor if you notice any changes such as:**

- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel

Additionally, you are advised to join mammography screening programs when offered to you.

**Ovarian cancer**

Ovarian cancer is rare – much rarer than breast cancer. The use of oestrogen-only HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

**Effect of HRT on your heart or circulation**

**Blood clots in a vein (thrombosis)**

The risk of **blood clots in the veins** is about 1.3 to 3-times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

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 unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m<sup>2</sup>)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see "Stop taking this medicine and see a doctor immediately".

**Compare**

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein. For women in their 50s who have been taking estrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

**Heart disease (heart attack)**

For women taking estrogen-only therapy there is no increased risk of developing a heart disease.

**Stroke**

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

**Compare**

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

**Other conditions**

HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, herbal medicines or other natural products. This is because this medicine can affect the way some other medicines work. Also some other medicines can affect the way this medicine works.