PACKAGE LEAFLET: INFORMATION FOR THE USER

OVESTIN® 1 mg CREAM

ESTRIOL 1mg in 1g of cream

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:

1. What Ovestin is and what it is used for
2. Before you use Ovestin
3. How to use Ovestin
4. Possible side effects
5. How to store Ovestin
6. Further information

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. It belongs to a group of medicines called Hormone Replacement Therapy (HRT).

What is Ovestin used for

Ovestin is used:

- For vaginal problems caused by having too little ‘oestrogen’
- Before or after vaginal surgery to help wound healing.

How Ovestin works

Estriol (the medicine in Ovestin) is one of the natural oestrogens.

- Oestrogens are female sex hormones.
- They are produced in the ovaries.
- They cause sexual development in women and control the menstrual cycle during the child-bearing years.

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 Ovestin which contain oestrogen. It may take several days or weeks before you notice an improvement.

2. Before you use Ovestin

As well as benefits, HRT has some risks that you need to consider when you're deciding whether to start taking it, or whether to carry on taking it. This is especially important if you are more than 60 years old.

Before you start taking HRT
Your doctor should ask about you and your family's medical history. Your doctor may decide to examine your breasts or your stomach and may do an internal examination. They will only do this if it is necessary for you or you have any special concerns.

→**Tell your doctor** if you have any medical problems or illnesses.

Regular check-ups
Once you have started on HRT, see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor may discuss the benefits and risks of continuing to take HRT.

Make sure that you:
- go for **regular breast screening** and **cervical smear** tests
- **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.

2.1 Do not use Ovestin if:

- you are allergic (hypersensitive) to any of the ingredients of Ovestin (listed in Section 6)
- you have had angina or a heart attack (myocardial infarction)
- you have had a blood clot (thrombosis)
- you have had breast cancer or suspect that you have breast cancer
- you have had cancer of other sex organs – such as cancer of the womb lining or ovary
- you have vaginal bleeding that has not been explained by your doctor
- you have excessive thickening of the womb lining
- you have had a liver disease, and your liver is still not working properly
- you have a rare blood problem called 'porphyria'.

→**Do not use this medicine** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Ovestin.

2.2 Take special care with Ovestin

Check with your doctor or pharmacist before using your medicine if you have had:
- a problem caused by growth of the womb lining outside the womb (fibroids or endometriosis)
- any problem with your heart or circulation (including high blood pressure or risk factors for a blood clot – see Section 2.4)
- relatives who have had blood clots
- asthma
- diabetes
- migraine or severe headaches
- epilepsy (fits)
- gallstones
- liver or kidney problems
- a rare problem called 'systemic lupus erythematosus' (SLE)
- otosclerosis (a hearing disorder).

→**If you have any of these,** talk to your doctor or pharmacist before using Ovestin.

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

2.3 Ovestin and the risk of developing cancer

Breast cancer

- **Women who have ever had breast cancer should not take HRT.**

Taking HRT slightly increases the risk of breast cancer. The risk is also slightly increased if you have a later menopause. The risk after the menopause for a woman taking oestrogen-only HRT for 5 years is about the same as for a woman of the same age who is still having periods over that time and not taking HRT. The risk for a woman who is taking oestrogen plus progestogen HRT is higher than for oestrogen-only HRT. However, oestrogen plus progestogen HRT is beneficial for the endometrium.

For all kinds of HRT, the extra risk of breast cancer goes up the longer you take it. However, it returns to normal about 5 years after stopping HRT.

Your risk of breast cancer is also higher if:

- you have a close relative (mother, sister or grandmother) who has had breast cancer
- you are seriously overweight.

How likely is breast cancer?
Looking at **women aged 50,** on average, by the time they reach 65:

- In women **not taking HRT: 32 in 1,000** will get breast cancer.
- In women who start taking **oestrogen-only HRT** at age 50 and take it for **5 years: between 33 and 34 in 1,000** will get breast cancer. This means **an extra 1 to 2 cases.**
- In women taking **oestrogen-only HRT for 10 years**: 37 in 1,000 will get breast cancer. This means **an extra 5 cases.**

If you notice any changes in your breast, such as: dimpling of your skin, changes in your nipple or any lumps you can see or feel:
→**Make an appointment to see your doctor** straight away.

Endometrial cancer (cancer of the lining of the womb)

Taking oestrogen-only HRT tablets for a long time can increase the risk of developing cancer of the lining of the womb. It is possible there may be a similar risk with oestrogen cream used directly in the vagina for repeated treatments or over a long time.

You do not need to take a separate progestogen with Ovestin.

If you get breakthrough bleeding or spotting, it is usually nothing to worry about, but you should:
→**Talk to your doctor.** It could be a sign that your endometrium has become thicker.

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 problem. Some studies have shown 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 increase the risk in the same way.

2.4 Ovestin and the heart or circulation

Heart disease
HRT is not recommended for women who 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 a progestogen, and a different oestrogen to the one in Ovestin) have shown that women may be slightly more likely to get heart disease during the first year of taking that type of HRT. For other types of HRT (like Ovestin), the risk is likely to be similar. However 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
Do not use any more HRT until a doctor says you can. This pain could be a sign of heart disease.

Stroke
Research suggests that HRT **slightly increases** the risk of having a stroke. Other things that can increase the risk of stroke include:

- getting **older**
- **high blood pressure**
- **smoking**
- drinking too much **alcohol**
- an uneven **heartbeat**

If you are worried about any of these things, or if you have had a stroke in the past, talk to your doctor to see if you should take HRT.

How likely is a stroke?
Looking at **women in their 50s**, on average, over 5 years

- In women **not taking HRT**: **3 in 1,000** would be expected to have a stroke.
- In women **taking HRT**: **4 in 1,000** would be expected to have a stroke.

Looking at **women in their 60s**, on average, over 5 years

- In women **not taking HRT**: **11 in 1,000** would be expected to have a stroke.
- In women **taking HRT**: **15 in 1,000** would be expected to have a stroke.

If you get an unexpected migraine-type headache, with or without disturbed vision:
→**See a doctor** straight away, and do not use any more HRT until a doctor says you can. These headaches may be an early warning sign of a stroke.

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

These blood clots are not always serious. However, if a clot travels to your lungs, it can cause chest pain, feeling breathless, collapse or even death. This is called a pulmonary embolism or PE.

You are more likely to get a blood clot if:

- you are **very overweight**
- you have had a **blood clot before**
- any of your **close family** have had **blood clots**
- you have ever had a **miscarriage**
- you have any **blood clotting problem** that needs treatment with a medicine such as warfarin
- you are off your feet for a long time because of **major surgery, injury or illness**
- you have a rare problem called **SLE**.

→If any of these things apply to you, talk to your doctor to see if you should take HRT.

How likely is a blood clot?
Looking at **women in their 50s**, on average, over 5 years:
• In women **not taking HRT**: **3 in 1,000** would be expected to get a blood clot.
• In women **taking HRT**: **7 in 1,000** would be expected to get a blood clot.

Looking at **women in their 60s,** on average, over 5 years:
• In women **not taking HRT**: **8 in 1,000** would be expected to get a blood clot.
• In women **taking HRT**: **17 in 1,000** would be expected to get a blood clot.

If you get painful swelling in your leg, sudden chest
pain or have problems breathing:
→**See a doctor** straight away

Do not use any more HRT until a doctor says you can. These may be signs of a blood clot.

2.5 Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Ovestin can affect the way some other medicines work. Also some other medicines can affect the way Ovestin works.

→**Tell your doctor** or pharmacist if you are taking any of the following:
- medicines for epilepsy - such as barbiturates, hydantoins and carbamezapine.
- medicines for infections - such as griseofulvin and rifamycins..
- medicines for viral infections - such as nevirapine, efavirenz, ritonavir or nelfinavir.
- herbal peparations containing St John's wort (*Hypericum perforatum*) - a herbal medicine used for depression.
- one of the following medicines: corticosteroids, succinylcholine,theophyllines or troleandomycin.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ovestin.

If you have a vaginal infection, your doctor may also prescribe a medicine to treat the infection.

2.6 Operations

→**Tell your doctor** you are using Ovestin if you are going to have surgery. You may need to stop using 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.

2.7 Pregnancy and breast-feeding

- Do not use Ovestin if you are pregnant or might become pregnant. This is because it may affect the baby.
- Do not breast-feed if you are using this medicine.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

2.8 Driving and using machines

Ovestin has no or little effect on the ability to drive or use machines.

3. How to use Ovestin

Always use Ovestin exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- If you have had your womb and ovaries removed, you can start using Ovestin straight away.
- If you have never used HRT before or if you are changing over from a period-free HRT, you can also use Ovestin straight away.
- If you are changing over from another type of HRT where you have a period, start taking Ovestin one week after you finish the other HRT.

3.1 How much to use

For vaginal problems

- The usual dose is 1 applicator up to the ring (0.5 mg estriol in 0.5 g of cream) a day for the first 2 to 3 weeks.
- Then the dose is 1 applicator up to the ring twice a week.

Your doctor will prescribe the lowest dose that relieves your symptoms. Your doctor may want you to stop from time to time (every 2 to 3 months for a period of 4 weeks). This is to check if you still need treatment.

Before or after vaginal surgery

- Before surgery - the dose is 1 applicator up to the ring (0.5 mg estriol in 0.5 g of cream) a day for 2 weeks before the operation.
- After surgery - do not use the cream again for at least 2 weeks. Then use 1 applicator up to the ring twice a week.

3.2 How to apply the cream

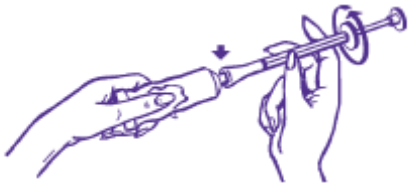
Ovestin comes in a pack together with a clear plastic applicator.

Use the applicator to apply the cream in the vagina. **A good time to do this is before going to bed.**

The applicator has a ring marked on the body. Fill the applicator up to the ring mark with Ovestin cream to get the correct dose.

→**Follow these instructions:**

1. Remove the cap from the tube and turn the cap upside down. Then use the sharp point to open the tube.
2. Screw the end of the applicator onto the tube



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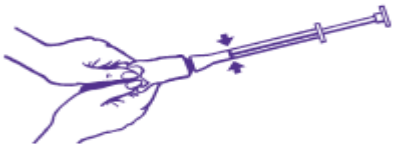
3. Squeeze the tube to fill the applicator with the cream up to the red ring mark (the plunger will stop at the red ring mark).



4. Unscrew the applicator from the tube and put the cap back on the tube.
5. To apply the cream, lie down, put the end of the applicator deep into your vagina and slowly push the plunger all the way in.

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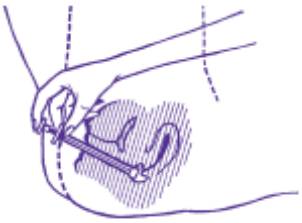

Cleaning the applicator

- After use, pull the plunger out of the barrel.
- Wash the plunger and barrel in hand hot, soapy water.
- Do not use detergents. Rinse well with clean water afterwards.
- Do not put the applicator in boiling water.

Ovestin is easy to remove with water.

3.3 If you use more Ovestin than you should or if you swallow it accidentally

If someone has swallowed some cream by accident, or too much cream is applied at any time, there is no need to worry. However, you should talk to your doctor. The person may feel sick or be sick. Women may have some vaginal bleeding after a few days.

3.4 If you forget to use Ovestin

- Apply the missed dose when you remember, unless you are more than 12 hours late.
- If you are more than 12 hours late just skip the missed dose.

3.5 If you stop using Ovestin

Keep using this medicine as prescribed by your doctor. Keep using Ovestin, even if you seem to be better. If you stop too early or too suddenly your problem may return.

4. Possible side effects

Like all medicines, Ovestin can cause side effects, although not everybody gets them.

→See your doctor straight away, if you notice any of the following serious side effects – your doctor may decide to stop you using the cream:

- your blood pressure rises
- your skin or the whites of your eyes go yellow (jaundice)
- you suddenly have migraine-type headaches (see Section 2.4 above)

- you have signs of a blood clot (see Section 2.4 above)
- you have any of the problems listed in Section 2.1 above.

These side effects are rare.

Other side effects include:

- irritation or itching of the skin in or around your vagina when you start to use Ovestin. This usually gets better after a few weeks.
- increased vaginal discharge, bleeding or spotting
- gall bladder problems
- skin problems such as a rash or an allergy to the sun
- breasts become swollen, tender or painful
- headaches
- feeling sick or being sick.

→If you have any of these side effects **tell your doctor**. They may decide to stop your treatment for a while.

Dementia
HRT will not prevent memory loss. In one study of women who started using combined HRT after the age of 65, a small increase in the risk of dementia was observed.

→If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, **tell your doctor or pharmacist.**

5. How to store Ovestin

Keep out of the reach and sight of children.
Do not use this medicine after the "use by" date on the pack.
Do not store above 25˚C. Do not freeze. .
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Ovestin contains

- The active substance is estriol. Each gram of cream contains 1 milligram of estriol.
- The other ingredients are chlorhexidine dihydrochloride, octyldodecanol, cetyl palmitate, glycerin, cetyl alcohol, stearyl alcohol, polysorbate 60, sorbitan stearate, lactic acid, sodium hydroxide and purified water.

What Ovestin cream looks like and the contents of the pack

- Ovestin is a white cream.
- There are 15 gm of cream in each tube.
- The pack contains a clear plastic applicator (Applicator CE 0336)

The Marketing authorisation holder is:
Aspen Pharma Trading Limited,
3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

The manufacturer is:
Organon (Ireland) Ltd., Drynam Road, Swords,
Co.Dublin, Ireland

This leaflet was last updated in September 2014

To listen to or request a copy of this leaflet in Braille, large print or audio
please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name: Ovestin 1 mg cream
Reference Number: PL 39699/0058
This is a service provided by the Royal National Institute for Blind People