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PACKAGE LEAFLET: INFORMATION FOR THE USER

OVESSE® 1 mg/g VAGINAL CREAM

ESTRIOL 1mg in 1g of cream

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- Your symptoms may take a few months to improve. Talk to your doctor or pharmacist if your symptoms worsen at any point, or if there has not been any improvement in your symptoms after 3 months of treatment.

In this leaflet:

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

1. What Ovesse is and what it is used for

The name of your medicine is Ovesse 1 mg/g vaginal cream. Ovesse contains a medicine called estriol. Ovesse belongs to a group of medicines called **local vaginal 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. The drop in oestrogen may cause the vaginal wall to become thinner, drier and less elastic and can cause symptoms in the vagina such as dryness, soreness or irritation, itching or burning sensation, and painful sexual intercourse.

Ovesse 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.

Ovesse is used to treat vaginal symptoms due to oestrogen deficiency in postmenopausal women aged 50 years and above, who have not had a period for at least 1 year. Such symptoms include:

- Vaginal dryness, soreness or irritation
- Vaginal itching or burning sensation
- Painful sexual intercourse

2. What you need to know before you use Ovesse

Medical history and Pharmacy review:

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.

Before you start (or restart) using Ovesse, your pharmacist will ask about your own and your family's medical history. They may also ask you about your menopause and what symptoms you have had. This is to make sure that Ovesse is suitable for you and that you do not need to see your doctor before using Ovesse or if any other treatments may be more suitable.

Once you have started on Ovesse you should review your treatment regularly with your pharmacist. Let your doctor know that you are using Ovesse at your next routine appointment.

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

Do not use Ovesse if any of the following applies to you. If you are not sure about any of the points below, talk to your pharmacist before using Ovesse.

Do not use Ovesse if you:

- are **allergic** (hypersensitive) to **estriol** or any of the other ingredients of Ovesse (listed in section 6)

- have or have ever had **womb or ovarian cancer**, or you have symptoms such as vaginal bleeding, or pain, bloating or swelling in your lower abdomen or pelvis that you have not told your doctor about
- have **had any vaginal or genital bleeding since your periods stopped due to the menopause**
- have recent or suspected endometrial hyperplasia (or e.g., if you have been referred for an ultrasound of your womb and are awaiting the results)
- have any change in the look/feel of the vulval area such as thickening or a lump, or if you have noticed any shrinking or scarring in this area
- have previously been treated with systemic oestrogen only HRT (without progestogen) and you have not had your womb removed (hysterectomy)
- have a condition called "**vulval dermatoses**" or you have any genital skin disorders such as severe vaginal itching or itchy patches or rash. Your pharmacist will ask questions to confirm if the level of itching is a sign of something other than vaginal atrophy
- have a **current vaginal infection** before starting treatment
- have or have ever had **breast cancer**, or if you are suspected of having it
- 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)
- have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**
- have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- have or ever have had a **liver disease** and your liver function tests have not returned to normal
- have a rare blood problem called "**porphyria**" which is passed down in families (inherited)

You may need to see your doctor before using Ovesse if any of the following apply to you. Tell your pharmacist if you:

- are receiving a type of HRT (including tablets or patches) that circulates in the blood.
- have a history of endometriosis.
- have a history of endometrial hyperplasia.
- are switching from another vaginal oestrogen HRT.

Warnings and precautions

Talk to your doctor or pharmacist if any vaginal infection develops while you are using Ovesse.

Stop using Ovesse and see a doctor immediately if you notice any of the following during treatment:

- any of the conditions mentioned in the 'DO NOT use Ovesse' section
- any **new** vaginal bleeding, spotting or itching
- if you have endometriosis and your symptoms come back
- Swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty in breathing which are suggestive of angioedema.

You must also seek prompt advice from your doctor if you notice any of the following during treatment:

- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- 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

Tell your doctor you are using this medicine

if you have or have ever had any of the following problems, and seek advice from them if any of these conditions return or get worse during treatment:

- uterine fibroids (leiomyoma)
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- increased risk of getting an oestrogen-sensitive cancer such as womb, ovarian or breast cancer (e.g. having a mother, sister or grandmother who has had any of these cancers)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- systemic lupus erythematosus, SLE (a disease of the immune system that affects many organs of the body)
- epilepsy
- asthma
- Otosclerosis (a disease affecting the eardrum and hearing)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- hereditary or acquired angioedema.

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

Taking oestrogen-only systemic 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 Ovesse if used for repeated or long term (more than one year) treatments. However, Ovesse has been shown to have very low absorption into the blood, therefore the addition of a progestogen is not necessary.

If you get any vaginal bleeding e.g. breakthrough bleeding or spotting, especially after using the product for some time, it may be nothing to worry about but you should stop using Ovesse and seek prompt advice from your doctor. It could be a sign that your endometrium has become thicker.

General Information – Risks associated with HRT

Ovesse is a **local vaginal HRT**. Other HRT medicines which circulate in the blood and are used to treat hot flushes and other menopausal symptoms are known as **systemic HRT**.

These are known to increase the risk of some conditions occurring, especially when used for a long time. It is thought that the risk of these conditions may not increase by as much with Ovesse as with systemic HRT, but this is not known for sure: **See section 4 for more detail on risk/side effects with systemic HRT.**

- **Breast cancer:** Evidence suggests that using Ovesse does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if Ovesse can be safely used in women who had breast cancer in the past.
 - Ovarian cancer.
 - Blood clots in a vein (thrombosis).
 - Heart disease (heart attack): For women taking oestrogen-only therapy there is no increased risk of developing heart disease.
- Stroke.

You should speak with your pharmacist or doctor if you are concerned.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

Ovesse is used for a local treatment in the vagina and is not likely to affect other medicines. Ovesse

may affect other vaginally applied treatments. Ask your pharmacist for advice if you are unsure.

Pregnancy and breast-feeding

Women who are pregnant or breast-feeding should not use Ovesse.

Driving and using machines

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

Ovesse contains cetyl alcohol and stearyl alcohol. These may cause local reactions.

3. How to use Ovesse

Always use Ovesse exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

This medicine is for **vaginal use** only. You will need to fill the applicator with cream from the tube yourself.

Treatment with Ovesse vaginal cream may be started on any day.

How much to use

- **Initial dose:** 1 applicator filled up to the red ring mark (0.5 mg estriol in 0.5 g of cream) a day for 2 weeks.
- **Maintenance dose:** 1 applicator filled up to the red ring mark twice a week (3 or 4 days between each dose).

Restarting treatment after a break

You can restart using Ovesse at any time provided it is still suitable and your overall health is unchanged.

- If you are still experiencing symptom relief after a break from treatment with Ovesse, it is recommended that treatment is restarted at the **maintenance dose**.
- If you are experiencing bothersome symptoms again after a break from treatment with Ovesse, it is recommended to restart treatment at the **initial daily dose regimen for 2 weeks**, followed by the twice weekly **maintenance dose**.

Do NOT use more than the recommended dose

How to apply the cream

Ovesse 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 red ring marked on the body.

ASPEN Artwork Panel

AW Version: 9	Page: 1 of 2
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New Item Code: 00002_0000138049

Previous Item Code: N/A

Market United Kingdom

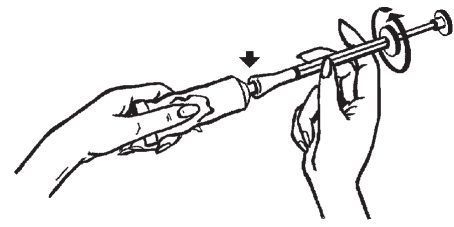
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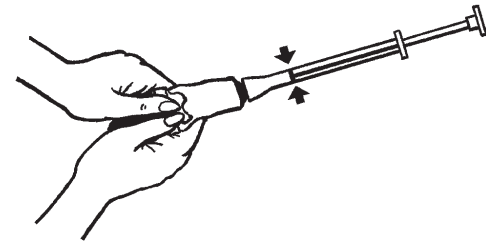
Fill the applicator up to the red ring mark with Ovesse vaginal cream to get the correct dose.

→ **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.

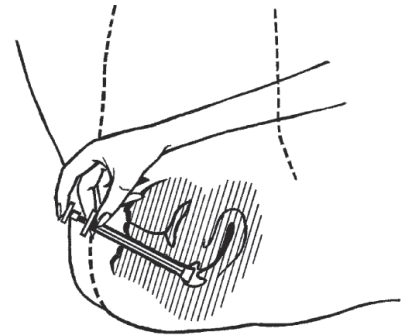


3. Squeeze the tube to fill the applicator with the cream up to the red ring mark (the plunger will stop at the red ring mark).



4. Unscrew the applicator from the tube and put the cap back on the tube.

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.



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.

Ovesse is easy to remove with water.

Speak to your pharmacist if you experience any difficulties with using the vaginal applicator.

If you use more Ovesse 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 or pharmacist. The person may feel sick or be sick. Women may have some vaginal bleeding after a few days.

If you forget to use Ovesse

If you forget a dose, use the medicine as soon as you remember. Do not use a double dose to make up for a forgotten dose.

If you stop using Ovesse

You can stop using Ovesse at any time, however, symptoms may return when you stop. Speak to your doctor if you want to try an alternative treatment.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are using Ovesse. You may need to stop using Ovesse about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start using Ovesse again.

4. Possible side effects

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

Stop using this medicine and seek urgent medical attention if you have a serious allergic reaction to Ovesse:

A serious allergic reaction may occur only very rarely. Signs may include:

- Suddenly feeling unwell with sweating;
- Vomiting;
- Difficulty in breathing;
- Rapid heartbeat or feeling dizzy.

Stop using Ovesse and seek prompt advice from your doctor if:

- You develop any **new** vaginal bleeding, spotting or itching

- You have endometriosis and your symptoms have come back

A vaginal infection develops while you are using Ovesse

Other side effects include:

- irritation or itching of the skin in or around your vagina when you start to use Ovesse. 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.
- flu-like symptoms

→ If you have any of these side effects **tell your doctor or pharmacist.**

Side effects reported with systemic HRT treatments:

HRT medicines which circulate in the blood and are used to treat hot flushes and other menopausal symptoms are known as 'systemic HRT'. These medicines include oral tablets and patches (transdermal patches) or gels which go on the skin. Systemic HRT increases the risk of some conditions occurring, especially when used for a long time (see below).

Ovesse contains a low dose of oestrogen which works locally in the vagina. **Ovesse is classed as a local vaginal HRT, not a systemic HRT. It is thought that the risks associated with local HRT's such as Ovesse are lower than those associated with systemic HRT's, although it is not known for sure.** Speak with your doctor or pharmacist if you are concerned.

Breast cancer

Evidence suggests that using Ovesse does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if Ovesse 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 or soreness of the skin (sometimes looking like an orange peel);
- changes in the nipple (such as discharge or the nipple turns inwards);
- unusual swelling in all or part of the breast, or any lumps or thickening 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 systemic HRT has been associated with a slightly increased risk of ovarian cancer.

Compare

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).

Blood clots in a vein (thrombosis)

The risk of blood clots in the veins is about 1.3 to 3-times higher in systemic 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/m²)
- 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.

Signs of a blood clot to look out for include:

- painful swelling and redness of the legs;
- sudden chest pain;
- difficulty in breathing.

If you observe any **signs of a blood clot**, stop using Ovesse and see your 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 oestrogen-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.

The following side effects have also been reported with systemic HRT treatments:

- gall bladder disease
- various skin disorders:
 - discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma)
 - painful reddish skin nodules (erythema nodosum)
 - rash with target-shaped reddening or sores (erythema multiforme)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ovesse

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.

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6. Further information

What Ovesse 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 Ovesse vaginal cream looks like and the contents of the pack

- Ovesse is a white cream.
- There are 15 grams of cream in each tube.
- The pack contains a clear plastic applicator

The Marketing authorisation holder is:

Aspen Pharma Trading Limited,
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Dublin 24, Ireland Tel: +44 (0)1 748 828 391

The manufacturer is:

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32-36, D-23843 Bad Oldesloe, Germany

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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: Ovesse 1 mg/g vaginal cream Reference Number: PL 39699/0118
This is a service provided by the Royal National Institute for Blind People



ASPEN Artwork Panel

AW Version: 9
Page: 2 of 2

New Item Code: 00002_0000138049

Previous Item Code: N/A

Market: United Kingdom

Number of Colours: 1

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150 mm Measuring Bar