

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Estriol 0.5 mg pessary**

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

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

#### **What is in this leaflet?**

1. What Estriol 0.5mg pessary is and what it is used for
2. What you need to know before you use Estriol 0.5mg pessary
3. How to use Estriol 0.5mg pessary
4. Possible side effects
5. How to store Estriol 0.5mg pessary
6. Contents of the pack and other information

#### **1. What Estriol 0.5mg pessary is and what it is used for**

The name of your medicine is Estriol 0.5 mg pessary. Estriol 0.5mg pessary contains a medicine called estriol. This medicine 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 Estriol 0.5mg pessary 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. What you need to know before you use Estriol 0.5mg pessary

### 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 estrogen-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.

### **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 use 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 is 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 this medicine, 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. In addition, some other medicines can affect the way this medicine works.

→ **Tell your doctor** or pharmacist if you are taking any of the following:

- medicines for epilepsy - such as barbiturates, hydantoins and carbamazepine.
- medicines for infections - such as griseofulvin and rifamycins.
- medicines for viral infections - such as nevirapine, efavirenz, ritonavir or nelfinavir.
- herbal preparations containing St John's wort (*Hypericum perforatum*) - a herbal medicine used for depression.
- one of the following medicines: corticosteroids, succinylcholine, theophyllines or troleandomycin.

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.

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

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

### **Operations**

→ **Tell your doctor** you are using this medicine 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.

### **Pregnancy, breast-feeding and fertility**

This medicine is for use in postmenopausal women only. If you become pregnant, stop taking this medicine and contact your doctor.

- Do not use this medicine 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.

### **Driving and using machines**

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

### **3. How to use Estriol 0.5mg pessary**

Always use this medicine 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 this medicine straight away.
- If you have never used HRT before or if you are changing over from a period-free HRT, you can also use this medicine straight away.
- If you are changing over from another type of HRT where you have a period, start taking this medicine one week after you finish the other HRT.

#### **How much to use**

##### *For vaginal complaints*

For vaginal complaints, the usual dosage is 1 pessary daily during the first weeks (maximally 4 weeks); later on the dose is gradually decreased to, for instance, 1 pessary twice a week.

Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

##### *If you need to have surgery*

If you are going to have surgery, tell the surgeon that you are using this medicine. You may need to stop using this medicine 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 this medicine again. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

##### *Before or after vaginal surgery*

For improving wound healing in postmenopausal women undergoing vaginal surgery the usual dose is 1 pessary daily in the 2 weeks before surgery; 1 pessary twice a week in the 2 weeks after surgery.

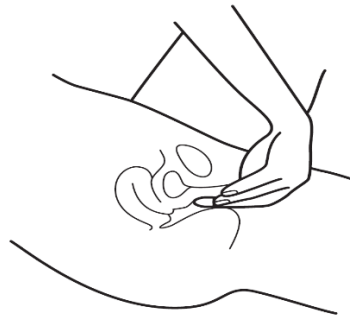
To help assess cervical smears taken from postmenopausal women the usual dose is 1 pessary on every other day in the week before taking the next smear.

##### *Inserting the pessary*

- Always wash your hands before and after inserting the pessary.
- Tear down the groove between two individually wrapped pessaries
- Remove one pessary from its plastic packet



- Lie down with your knees bent and spread apart
- Use your finger to push the pessary as deep as possible into the vagina



- It is a good idea to do this before retiring at night.

This medicine is not intended to insert into the rectum (back passage).

**If you use more Estriol 0.5mg pessary than you should**

If you may have used more Estriol 0.5mg pessary than you should, talk to a doctor or pharmacist.

**If someone has swallowed some pessaries**

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.

**If you forget to use this medicine**

- 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.

Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.



#### 4. Possible side effects

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

The following diseases are reported more often in women using HRT, which circulate in the blood compared to women not using HRT. These risks apply less to vaginally administered treatments such as this medicine:

- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see Section 2.

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

- 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 this medicine. 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**. 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.**

The following side effects have been reported with other HRTs:

- 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](http://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 Estriol 0.5mg pessary**

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package to protect from light and moisture.

Do not use this medicine after the expiry date, which is stated on the carton after (EXP). The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What this medicine contains**

The active substance of this medicine is estriol. The other ingredient is Ovucire 3460U (containing hard fat with additives, glyceryl ricinoleate and macrogol cetostearyl ether).

### **What this medicine looks like and contents of the pack**

White, approximately 14 mm x 25 mm, torpedo-shaped pessary. Each carton contains 15 or 30 pessaries.

Not all pack sizes may be marketed.

### **The Marketing Authorisation Holder is:**

Aspen Pharma Trading Limited,  
3016 Lake Drive, Citywest Business Campus,  
Dublin 24,  
Ireland

### **The Manufacturer is:**

Unither Industries,  
Z.I. Le Malcourlet,  
03800 Gannat,  
France

**This leaflet was last revised in October 2023.**

**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: Estriol 0.5mg pessary

Reference Number: PL 39699/0113

This is a service provided by the Royal National Institute for Blind People