

# ESTRO-PESS pessary

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ESTRO-PESS?

ESTRO-PESS contains the active ingredient estradiol (as hemihydrate). ESTRO-PESS is a local hormone replacement therapy (HRT) used to treat a condition called atrophic vaginitis.

For more information, see Section [1. Why am I using ESTRO-PESS?](#) in the full CMI.

### 2. What should I know before I use ESTRO-PESS?

Do not use if you have ever had an allergic reaction to ESTRO-PESS or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ESTRO-PESS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ESTRO-PESS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ESTRO-PESS?

- The usual dose of ESTRO-PESS is 1 pessary each day for the first two weeks, then one pessary twice a week.
- The ESTRO-PESS pessary should be inserted into your vagina using the applicator (see the diagrams included in the 'Directions for Use' section of this leaflet).

More instructions can be found in Section [4. How do I use ESTRO-PESS?](#) in the full CMI.

### 5. What should I know while using ESTRO-PESS?

<b>Things you should expect</b>	<ul style="list-style-type: none"><li>• You can expect your symptoms to improve within a few weeks of starting ESTRO-PESS.</li><li>• ESTRO-PESS is not a contraceptive and will not prevent pregnancy.</li></ul>
<b>Things you should do</b>	<ul style="list-style-type: none"><li>• See your doctor regularly for checkups while using ESTRO-PESS</li><li>• Tell your doctor immediately if you become pregnant while using ESTRO-PESS.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not change the way you use ESTRO-PESS, or change the dosage, without checking with your doctor.</li><li>• Do not swallow ESTRO-PESS. These modified release pessaries are for vaginal use only.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep ESTRO-PESS in a cool dry place, away from moisture or heat, where the temperature stays below 25°C. Do not refrigerate.</li></ul>

For more information, see Section [5. What should I know while using ESTRO-PESS?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects of ESTRO-PESS include headaches, abdominal pain, and vaginal bleeding, discharge, or discomfort. If you notice any of these common side effects, speak to your doctor. In rarer cases, a serious side effect may occur. These involve severe pain or swelling in your legs, or sudden chest pain and difficulty breathing, yellowing of the skin and eyes (jaundice), and a migraine-like headache (with no prior history of migraines). More serious side effects are listed in Section [6. Are there any side effects?](#) If you notice any of these serious side effects, call your doctor straight away or go to the Emergency Department at your nearest hospital, as you may need urgent medical attention. Taking HRT is associated with an increased risk of certain cancers, and cardiovascular disease (e.g. heart disease, stroke, blood clots).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ESTRO-PESS pessary

Active ingredient: *estradiol (as hemihydrate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ESTRO-PESS.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ESTRO-PESS.

Where to find information in this leaflet:

- [1. Why am I using ESTRO-PESS?](#)
- [2. What should I know before I use ESTRO-PESS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ESTRO-PESS?](#)
- [5. What should I know while using ESTRO-PESS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ESTRO-PESS?

ESTRO-PESS contains the active ingredient estradiol (as estradiol hemihydrate). The estradiol in ESTRO-PESS is identical to the estradiol produced in the ovaries of women and is classified as a natural estrogen.

ESTRO-PESS is a local hormone replacement therapy (HRT) used to treat a condition called atrophic vaginitis. The symptoms include dryness and irritation in the vagina and pain during sexual intercourse. Atrophic vaginitis is caused by a loss of the female sex hormone, estrogen, which occurs around the menopause. When placed in the vagina, ESTRO-PESS gradually releases estradiol. This may relieve discomfort in the vagina.

**Ask your doctor if you have any questions about why ESTRO-PESS has been prescribed for you.**

Your doctor may have prescribed ESTRO-PESS for another reason.

## 2. What should I know before I use ESTRO-PESS?

### Warnings

**Do not use ESTRO-PESS if:**

- you have, you are suspected of having, or you have had breast cancer.**
- you have, you are suspected of having, or you have had cancer which is sensitive to estrogens, such as cancer of the lining of the womb (endometrium).**
- you have any unexplained vaginal bleeding.**

- you have excessive thickening of the lining of the womb (endometrial hyperplasia) that is not being treated.**
- 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)**
- you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency).**
- you have or have previously had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina.**
- you have or have had a liver disease, and your liver function tests have not returned to normal.**
- you have a rare blood problem called 'porphyria', which is passed down in families.**
- you are pregnant or suspect you may be pregnant.**
- you are breast-feeding.**
- you are allergic to estradiol, or any of the ingredients listed at the end of this leaflet.**  
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- the expiry date printed on the pack has passed.**
- the packaging is torn or shows signs of tampering.**

**ESTRO-PESS should not be used in children or by males.**

**Stop using this medicine and consult your doctor immediately if any of the above conditions appear for the first time while using ESTRO-PESS.**

### 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.

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.

Once you've started on ESTRO-PESS, you should see your doctor for regular check-ups (3-6 months after starting ESTRO-PESS, and at least once a year thereafter).

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

There is only limited experience of treating women older than 65 years' with ESTRO-PESS.

Vaginal infections should be treated before ESTRO-PESS are used.

## Check with your doctor if you:

- **have or have had any of the following health conditions:**
  - asthma
  - epilepsy
  - diabetes
  - gallstones
  - high blood pressure
  - migraines or severe headaches
  - a liver disorder, such as a benign liver tumour
  - growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
  - a disease affecting the eardrum and hearing (otosclerosis)
  - a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
  - increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
  - increased risk of developing blood clots (see 'Blood clots in a vein (thrombosis)')
  - fibroids inside your womb
  - a very high level of fat in your blood (triglycerides)
  - fluid retention due to cardiac or kidney problems.

**Stop using ESTRO-PESS and see a doctor immediately if you experience any unexplained vaginal bleeding, or persistent or recurrent vaginal bleeding.**

## Pregnancy and breastfeeding

**Talk to your doctor if you are pregnant, plan to be pregnant or if you are breastfeeding.**

## Risks associated with HRT

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

**The following risks apply to HRT medicines in general, which circulate in the blood. It is not known how these risks apply to locally administered treatments such as ESTRO-PESS.**

### HRT and cancer

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

Taking estrogen-only HRT tablets for a long time can increase the risk of developing cancer of the womb lining, the endometrium. It is uncertain whether long term (more than one year) or repeated use of local vaginally administered estrogen products possess a similar risk.

If you get breakthrough 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.

Compare:

In women who still have a womb and who are not taking HRT, on average, 5 in 1,000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a womb and who take estrogen-only HRT, between 10 and 60 women in 1,000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

*Breast cancer:*

Evidence suggests that taking combined estrogen-progestagen and possibly also estrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

For women who have had their womb removed and who are using estrogen-only HRT for 5 years, little or no increase in breast cancer risk is shown.

Compare:

Women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1,000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking estrogen-progestagen HRT over 5 years, there will be 13 to 23 cases in 1,000 users (i.e. an extra 4 to 6 cases).

**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 dimpling of the skin.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

*Ovarian cancer:*

Ovarian cancer is rare, much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestagen 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 2,000 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 2,000 users (i.e. about 1 extra case).

### Effect of HRT on the heart and 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
- 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.

**If you notice signs of a blood clot stop using HRT 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 1,000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking estrogen-progestagen HRT for over 5 years, there will be 9 to 12 cases in 1,000 users (i.e. 5 extra cases).

For women in their 50s who have had their womb removed and have been taking estrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1,000 users (i.e. 1 extra case).

*Heart disease (heart attack):*

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use estrogen-progestagen HRT are slightly more likely to develop heart disease than those not taking any HRT.

For women who have had their womb removed and are 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 1,000 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 1,000 users, over 5 years (i.e. 3 extra 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.**

### **3. What if I am taking other medicines?**

**Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ESTRO-PESS.**

ESTRO-PESS contains a very small amount of hormone which should not interact with other medicines you are using.

### **4. How do I use ESTRO-PESS?**

ESTRO-PESS is suitable for women who have had their womb removed (have had a hysterectomy) as well as for those who have not.

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

The usual dose of ESTRO-PESS is 1 pessary each day for the first two weeks, then one pessary twice a week (allowing three to four days between doses).

#### **When to use ESTRO-PESS**

- You can start treatment with ESTRO-PESS on any convenient day.
- Your doctor will tell you for how long you should use ESTRO-PESS.

#### **How to use it**

- The ESTRO-PESS pessary is inserted into your vagina using the applicator (see the diagrams included in the 'Directions for Use' section of this leaflet).
- ESTRO-PESS treatment should not affect your normal hygiene routine or lifestyle.

#### **If you forget to use ESTRO-PESS**

**If you forget to use ESTRO-PESS at the usual time, insert your pessary as soon as you remember.**

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

#### **If you use too much ESTRO-PESS**

If you think that you have used too many pessaries, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

An overdose of this medicine may cause nausea and vomiting.

## 5. What should I know while using ESTRO-PESS?

- You can expect your symptoms to improve within a few weeks of starting ESTRO-PESS.
- ESTRO-PESS can be stopped at any time. You should discuss this with your doctor.
- ESTRO-PESS is not a contraceptive and will not prevent pregnancy.

### Things you should do

- After starting ESTRO-PESS, you should see your doctor for regular check-ups (3-6 months after starting ESTRO-PESS, and at least once a year thereafter).
- **Stop using ESTRO-PESS and see a doctor immediately if you become pregnant while using ESTRO-PESS.**

### Things you should not do

- **Do not give this medicine to anyone else, even if their symptoms seem like yours.**
- **Do not use ESTRO-PESS to treat any other complaints unless your doctor tells you to.**
- **Do not change the way you use ESTRO-PESS, or change the dosage, without checking with your doctor.**
- **Do not swallow ESTRO-PESS.**  
This medicine is for vaginal use only.

### Looking after your medicine

Keep ESTRO-PESS pessaries in the original carton protected from light.

Store this medicine in a cool dry place away from moisture or heat, where the temperature stays below 25°C.

For example, do not store it:

- in the refrigerator
- in the bathroom or near a sink, or
- in the car on a hot day.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• genital infection with a fungus (thrush)</li> <li>• headache</li> <li>• stomach pain</li> <li>• feeling sick (nausea)</li> <li>• vaginal bleeding, discharge or discomfort</li> <li>• rash</li> <li>• weight increase</li> <li>• rise in blood pressure</li> <li>• hot flush.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious, common side effects.</b></p>

### Very rare side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• breast cancer, or cancer of the lining of the womb</li> <li>• excessive growth of the lining of the womb</li> <li>• allergic reaction</li> <li>• fluid retention</li> <li>• depression</li> <li>• trouble sleeping</li> <li>• worsening of migraine, where you have had migraines in the past</li> <li>• blood clots (deep vein thrombosis, DVT)</li> <li>• diarrhoea</li> <li>• hives, extensive rash</li> <li>• itching of the genital area</li> <li>• vaginal irritation or pain, painful spasm of the vagina or vaginal ulceration</li> <li>• increase in blood estrogen (blood test result).</li> </ul>	<p><b>Speak to your doctor if you have any of these very rare side effects.</b></p>

### Reasons for immediate withdrawal

Reasons for immediate withdrawal	What to do
<ul style="list-style-type: none"> <li>• refer to any of the conditions in section 2. "<i>What should I know before I use ESTRO-PESS?</i>"</li> <li>• signs of a blood clot. Symptoms include severe pain or swelling in your legs or sudden chest pain and difficulty breathing</li> <li>• yellow colouring of the skin and eyes (jaundice) or other liver problems</li> <li>• migraine-like headache, and you have not previously had migraines</li> <li>• significant increase in blood pressure. Symptoms include headache, tiredness and dizziness</li> <li>• pregnancy.</li> </ul>	<p><b>Tell your doctor immediately.</b></p> <p>You may be told to stop using ESTRO-PESS if any of these conditions occur.</p>

**Tell your doctor if you are not feeling well, find any side effect too uncomfortable or unacceptable or if any side effect becomes worse.**

Cancer of the breast, ovaries or the lining of the womb, blood clots and stroke have been reported with some types of systemic hormone replacement therapy ("systemic" means to affect the body as a whole).

The following additional side effects have been reported to be associated with other types of estrogen treatment:

- heart attack or heart disease
- gall bladder disease
- various skin diseases and itching
- increase in size of uterine fibroids
- epilepsy
- libido disorder
- asthma
- probable dementia.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ESTRO-PESS contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• Each modified release pessary contains estradiol (as hemihydrate) 10 microgram</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• hypromellose</li><li>• lactose monohydrate</li><li>• maize starch</li><li>• magnesium stearate</li><li>• macrogol 6000.</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• sugars as lactose.</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ESTRO-PESS looks like

ESTRO-PESS is a white, round, film coated tablet embossed with "E" one side and plain on the other side. The tablet is a modified release pessary designed for internal vaginal use. Available in blister packs of 18 pessaries with 6 reusable applicators.

**Do not dispose of the applicators until all the tablets in the pack have been used.**

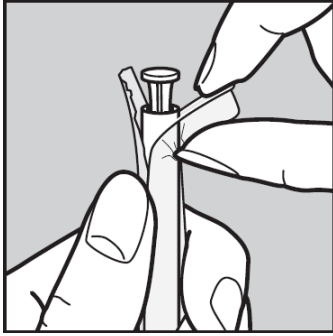
Australian Registration number: AUST R 339050

### Who distributes ESTRO-PESS

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
Australia

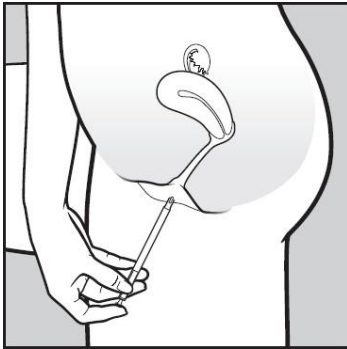
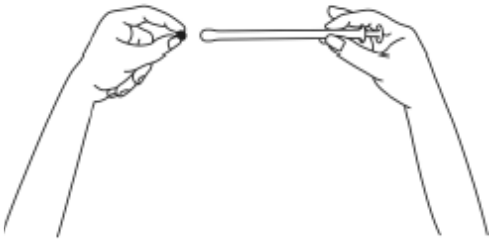
This leaflet was revised in September 2025.

# Directions for Use

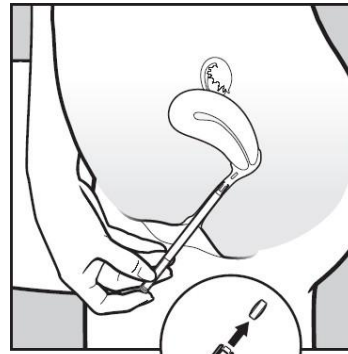


1. Wash hands well. Take out the applicator. Open the end as shown in the picture.

2. Pull the plunger out of the applicator until it comes to a stop.  
Remove one vaginal tablet from the enclosed blister pack and insert into the applicator as follows:  
Place the vaginal tablet firmly in the holder of the applicator end (wide end).



3. Insert the applicator carefully into the vagina. Stop when you can feel some resistance (8-10 cm).



4. To release the pessary, gently press the push button until you feel a click. The pessary will stick to the wall of the vagina straight away. It will not fall out if you stand up or walk.

5. Take out the applicator and follow the washing instructions below.

## After each use, clean the applicator as follows:

1. Withdraw the plunger from the applicator.
2. Clean both parts (tube and plunger) with mild soap and rinse with warm tap water for 5 seconds. Rinse the tube's inner and outer surface.
3. If necessary, remove larger amounts of remaining water from both parts (tube and plunger) by shaking off the water.
4. Air dry both parts (tube and plunger) on a clean surface (e.g. clean paper fleece)
5. Introduce the plunger again in the applicator-tube for the next use of the applicator.
6. The vaginal tablet applicator can be used for up to 24 times for one single patient. Remove the applicator when the pack is empty and dispose of as household waste. Do not use applicators that show obvious signs of damage.