**Package leaflet: Information for the user**

**Estradiol 10 micrograms vaginal tablets**

estradiol

**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 any further questions, 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. See section 4.

**What is in this leaflet**


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


## 1. What Estradiol is and what it is used for

- Estradiol is a female sex hormone.
- It belongs to a group of hormones called oestrogens.
- It is exactly the same as the estradiol produced by the ovaries of women.

Estradiol belongs to a group of medicines called 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.

Estradiol 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.

The experience of treating women older than 65 years is limited.

## 2. What you need to know before you use Estradiol

**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 internal examination, if necessary.

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

Go for regular breast screening as recommended by your doctor.

**Do not use Estradiol:**
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 Estradiol.

Do not use Estradiol if:

- You are **allergic** (hypersensitive) to **estradiol** or any of the other ingredients of Estradiol (listed in section 6).
- You have or have ever had **breast cancer**, or you are suspected of having it.
- You have or have ever had **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or you are suspected of having it.
- You have **any unexplained vaginal bleeding**.
- You have excessive **thickening of the womb lining** (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 recently had a disease caused by blood clots in the arteries, such as a **heart attack, stroke** or **angina**.
- You have or have ever 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 (inherited).

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

**Warnings and precautions**
Talk to doctor ot pharmacist before taking Estradiol.
Tell your doctor if you have or have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Estradiol. If so, you should see your doctor more often for check-ups.

- 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 oestrogen-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

- Hereditary and acquired angioedema.

**Stop using Estradiol and see a doctor immediately**
If you notice any of the following when using HRT:
- Migraine-like headaches which happen for the first time
- 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)
- Any of the conditions mentioned in the 'Do not use Estradiol' section above
- 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:** Estradiol 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 Estradiol when it is used for repeated or long term (more than one year) treatments. However, Estradiol has shown to have very low absorption into the blood, and therefore the addition of a progestagen is not necessary.

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.

*The following risks apply to hormone replacement therapy (HRT) medicines which circulate in the blood. However, Estradiol 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 Estradiol, but you should see your doctor if you are concerned.*

**Breast cancer**
Evidence suggests that using Estradiol does not increase the risk of breast cancer in women who had no breast cancer in the past. It is not known if Estradiol 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.

*Compare*
The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who do not take 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 are about 3 cases per 2,000 users (i.e. about 1 extra case).

**Effect of HRT on 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 (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.

For signs of a blood clot, see 'Stop using Estradiol and see a doctor immediately'.

*Compare*
Looking at women in their 50s who do not take 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 oestrogen-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)**
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 increases with age.

*Compare*
Looking at women in their 50s who do not take 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 take 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.

**Other medicines and Estradiol**
Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription, herbal medicines or other natural products. However, Estradiol is used for a local treatment in the vagina and is not likely to affect other medicines. Estradiol may affect other vaginally applied treatments.

**Pregnancy and breast-feeding**

Estradiol is for use in postmenopausal women only. If you become pregnant, stop using Estradiol and contact your doctor.

**Driving and using machines**
No known effect.

## 3. How to use Estradiol

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Using this medicine**
- You can start using Estradiol on any day which is best for you.
- Insert the vaginal tablet into your vagina with the applicator.

The 'USER INSTRUCTIONS' at the end of the leaflet will tell you how to do this. Read the instructions carefully before using Estradiol.

**How much to use**
- Use one vaginal tablet each day for the first 2 weeks.
- Then use one vaginal tablet twice a week. Leave 3 or 4 days between each dose.

**General information about treating symptoms of the menopause:**

- Your doctor will aim to prescribe the lowest dose of Estradiol to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.
- Treatment should only be continued if the benefit is greater than the risk. Talk to your doctor about this.

**If you use more Estradiol than you should**
- If you have used more Estradiol than you should, talk to a doctor or pharmacist.
- Estradiol is for local treatment inside the vagina. The dose of estradiol is so low that a considerable number of tablets would have to be taken to approach the dose normally used for treatment taken by mouth.

**If you forget to use Estradiol**
- 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 Estradiol**
Do not stop using Estradiol without talking to your doctor. Your doctor will explain the effects of stopping treatment. He or she will also discuss other possibilities for treatment with you.

**If you need to have surgery**
If you are going to have surgery, tell the surgeon that you are using Estradiol. You may need to stop using Estradiol 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 Estradiol again.

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 medicines which circulate in the blood compared to women not using HRT. These risks apply less to vaginally administered treatments such as Estradiol:

- 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, 'What you need to know before you use Estradiol'.

**Common: may affect up to 1 in 10 people**

- Headache
- Stomach pain
- Vaginal bleeding, discharge or discomfort.

**Uncommon: may affect up to 1 in 100 people**

- An infection of the genitals caused by a fungus
- Feeling sick (nausea)
- Rash
- Weight increase
- Hot flush
- Hypertension.

**Not known (cannot be estimated from the available data)**

- Diarrhoea
- Fluid retention
- Migraine aggravated
- Generalised hypersensitivity (e.g. anaphylactic reaction/shock)
- Having trouble sleeping
- Vaginal and genital itching
- Itching
- Hives
- Allergic reaction at the application site such as genital rash
- Injury associated with device
- The medicine does not work

**The following side effects have been reported with systemic oestrogen treatment:**

- 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).

**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 the 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 Estradiol

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

Do not use this medicine after the expiry date which is stated on the carton label and blister 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.
This medicine may cause risk to the aquatic environment.

## 6. Contents of the pack and other information

**What Estradiol contains**
- The active substance(s) is estradiol (as estradiol hemihydrate). Each vaginal tablet contains 10 micrograms estradiol as estradiol hemihydrate.
- The other ingredients are: hypromellose, lactose monohydrate, maize starch and magnesium stearate.
- The film coating contains: hypromellose and macrogol.

**What Estradiol looks like and contents of the pack**
The vaginal tablets are white, round, film coated tablets embossed with "E" on one side and plain on the other side.

Pack sizes:
18 vaginal tablets per blister with two multiple use applicators.
24 vaginal tablets per blister with two multiple use applicators.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Mercury Pharmaceuticals Limited
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom.

**Manufacturer**
Haupt Pharma Münster GmbH (Member of the Aenova Group)
Schleebrüggenkamp 15
48159 Münster
Germany

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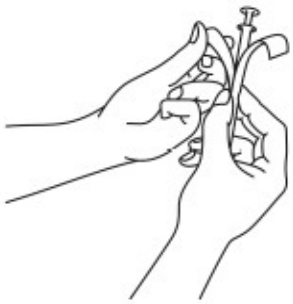
**USER INSTRUCTIONS**

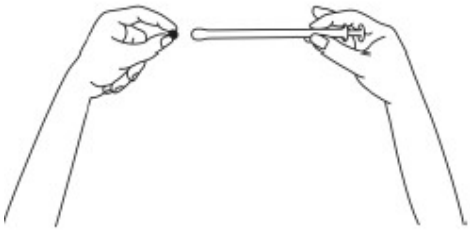
**How to use Estradiol 10 micrograms vaginal tablets**

1. Remove the applicator from its packaging.

   Open the end as shown in the picture.

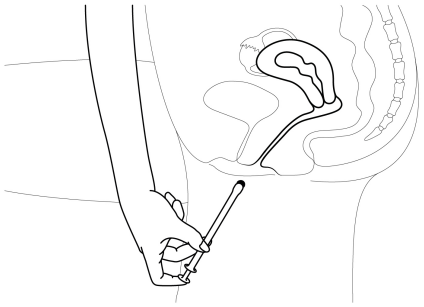


2. Gently pull the plunger out of the applicator until it comes to a stop.
3. Take a vaginal tablet from the separate blister and place it firmly in the holder of the applicator end (wide end)

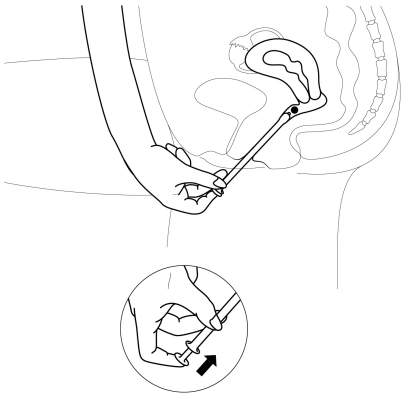


4. Insert the applicator carefully into the vagina.

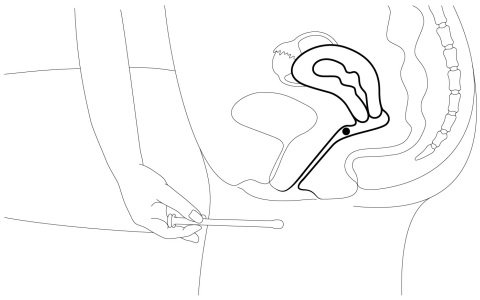
   Stop when you can feel some resistance (8–10 cm).



5. Release the vaginal tablet by slowly pressing the push-button until the end of the plunger stops.



The tablet will stick to the wall of the vagina straight away. It will not fall out if you stand up or walk.



6. After each use and before it is used again, clean the applicator according to the following cleaning procedure:

   - Remove the plunger from the applicator.

   - Clean both parts (tube and plunger) with mild soap and rinse with warm tap water for 5 seconds. Rinse the tubes inner and outer surface.

   - If necessary, remove larger amounts of remaining water from both parts (tube and plunger) by short shaking-off the water.

   - Air dry both parts (tube and plunger) on a clean surface (e.g. clean paper fleece).

   - Introduce the plunger again in the applicator-tube for the next use of the applicator.

7. Use the applicator until you have completed the treatment pack. Thereafter throw it away. If required, an additional applicator is included in the pack.