

You have received this patient
information from your doctor/nurse.

PATIENT INFORMATION

Treatment with
Estro[®]gel (estradiol)



Symptoms of estrogen deficiency

Estrogen is one of the female sex hormones and is primarily produced in the ovaries. The hormone is of great importance to several organs in the female body and has several physiological functions. Among other things, estrogen affects the genitals, bones, heart and brain.

During menopause, estrogen production decreases and for many women this can lead to deficiency symptoms such as:

- » hot flushes
- » vaginal dryness
- » sweats
- » urinary tract problems
- » mood swings
- » joint pain
- » sleep problems
- » fragile bones

These symptoms can often be alleviated with the use of estrogen, also known as Menopausal Hormone Therapy (MHT).

Treatment with Estro[®]gel

What is Estro[®]gel?

Estro[®] is a colourless gel that contains a form of estrogen known as estradiol. This is the same estradiol as naturally produced in your body. After application, estradiol is absorbed into the subcutaneous tissue, where it slowly enters the bloodstream and replaces the estrogen that the body can no longer produce.

Women who still have their uterus (womb) are recommended concurrent treatment with a progestogen. This is done in consultation with your doctor.

The recommended dose of Estro[®] is 1.25 g of gel (equivalent to 0.75 mg of estradiol) once a day. Your doctor will prescribe the lowest effective dose, for the shortest possible duration, to treat your symptoms.

Contact your doctor if you find the effect of the prescribed dose to be too strong or too weak.



How to use Estrogel®

Estrogel® pump bottle



Estrogel® pump bottle

Before use

Before you start using a new pump bottle of gel, you first need to activate the pump by pressing the plunger down. This first dose should be discarded.

Dosing

Remove the protective cap. Hold the bottle in one hand, press the plunger all the way down and let the gel run into the palm of your other hand. One press on the plunger corresponds to 1.25 g of gel and contains 0.75 mg of estradiol. Seal the cap carefully after each use.



Applying the gel

Use your hand to spread the gel **over as large an area of skin as possible** on your shoulders and arms, or the insides of your thighs, either in the morning or evening after washing. Avoid direct contact with the breast and genital areas. Also, do not apply the gel directly to mucous membranes, irritated or damaged skin. The gel does not need to be massaged or rubbed into the skin. Always wash your hands thoroughly with soap and water after applying the gel.

Allow the gel to dry for about 5 minutes before getting dressed. If your skin feels sticky after 5 minutes, the gel has been applied over an area that is too small. Next time, apply the gel over a larger area of skin. Wait at least one hour before washing or using skincare products on the treated skin area.



Avoid transferring Estrogel® to other people

- » Do not allow other people to apply the gel to your skin.
- » Avoid skin contact with others for one hour after application. Wear clothing that covers the area if necessary.
- » Extra caution is required when in close contact with children. In case of contact, wash the child's skin with soap and water as soon as possible. Seek medical attention if you see signs of unexpected puberty (e.g. onset of breast development) in a child who has been exposed to Estrogel®.



Overdose

If you have used too much Estrojel®, you may experience symptoms such as breast tenderness, vaginal bleeding or nausea. In such cases, contact your doctor as soon as possible.



If you have forgotten to use Estrojel®

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

- » If the next dose is *less* than 12 hours away, skip the dose you missed and apply your next dose when you are meant to, as usual.
- » If the next dose is *more* than 12 hours away, apply the missed dose, and then apply the following dose at the normal time the following day.



Side effects

Like all medicines, Estrojel® can cause side effects. Possible side effects are presented in more detail in the package leaflet. Contact your doctor as soon as possible if you experience any side effects.



Estrojel® and other medicines

Estrojel® can interact with other medicines, including over-the-counter medications. Therefore, it is important that you tell your doctor what other medicines you are taking while being treated with Estrojel®.



How to store Estrojel®

Estrojel® should be kept out of the sight and reach of children.



Package leaflet

Always follow the instructions given by your doctor. For more information, see the package leaflet. Read it carefully.

For more information about this product, please visit www.fass.se

EstroGel (estradiol) 0.75 mg/dose transdermal gel. Prescription medicine.

What EstroGel is used for: EstroGel is used for menopausal symptoms in women who have had their last natural period at least 6 months ago.

Do not use EstroGel: if you have or have ever had breast cancer, or if you suspect having it; if you have cancer which is sensitive to estrogens, such as cancer of the womb lining (endometrium), or if you suspect 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 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 have ever 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 estradiol or any other ingredients of this medicine. If any of the above conditions appear for the first time while using EstroGel, stop using it at once and consult your doctor immediately.

Once you start using EstroGel, you should have regular check-ups (at least once a year) with your doctor. Discuss the benefits and risks of continuing to use EstroGel with your doctor at these check-ups.

Stop using EstroGel and contact a doctor immediately if you notice any of the following during your HRT treatment: any of the conditions listed under "Do not use EstroGel"; yellowing of the skin or the whites of the eyes (jaundice), which can be a sign of liver disease; dramatic increase in blood pressure (possible symptoms include headache, fatigue and dizziness); migraine-like headache for the first time; if you become pregnant; signs of a blood clot, such as painful swelling and redness in your legs, sudden chest pain or breathing difficulties. **Irregular bleeds:** You may experience irregular vaginal bleeds or spotting during the first 3 to 6 months of your treatment with EstroGel. If these irregular bleeds continue for more than 6 months, start when you have used EstroGel for more than 6 months, or continue after you have stopped using EstroGel, contact your doctor as soon as possible. **Unexpected bleeds:** If you are using EstroGel together with a progestogen (i.e. progesterone), you will experience a vaginal bleed once a month (known as withdrawal bleeds). However, if you develop unexpected spotting between your monthly bleeds that continues for longer than the first 6 months, starts when you have been using EstroGel for more than 6 months, or continues after you have stopped using EstroGel, contact your doctor as soon as possible.

Read the package leaflet carefully before starting your treatment with EstroGel®