

Oestradiol

Oestradiol

Consumer Medicine Information

Before administration of this medicine please read this leaflet carefully. If you have any questions or worries, ask your doctor or pharmacist

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The name of your medicine is Oestradiol.
A doctor's prescription is required to obtain this medicine.

This leaflet answers some common questions about Oestradiol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Keep this information with the pack.
You may wish to read it again.

General advice

This medicine has been prescribed only for your current medical problem. It should not be used for other medical conditions.

Never give your medicine to anyone else and do not use medicines meant for other people. Tell every doctor treating you what medicines you are taking. Always carry a medical information card stating which medicines you are using. This can be very important if for example you are involved in an accident.

Return unused medicines to your pharmacy for disposal.

Make sure that other people who live with you or who look after you read this information.

What Oestradiol is used for

During and after the menopause the production of sex hormones by the body decreases. Women may then suffer from complaints such as hot flushes, night sweats, vaginal irritation, depression, and loss of sexual desire. Oestradiol can be used for the short-term relief of menopausal complaints.

It can also relieve these symptoms in women who have had their ovaries removed. Relief of symptoms usually starts within a few weeks, but optimal results are obtained after three months of treatment. Oestradiol is not intended for contraceptive use.

If you have not had a hysterectomy, your doctor will probably combine the Oestradiol treatment with another hormone product, a progestogen. This would be for about 10 to 14 days per month.

Before you use Oestradiol

Oestradiol may not be suitable for you if you suffer from certain medical conditions.

Before you start to use Oestradiol make sure you tell your doctor if you answer YES to any of the following questions: -

- are you pregnant or do you think you may be pregnant?
- do you have a tumour (e.g. a breast tumour or a tumour in your womb)?
- do you have or have you ever had heart disease or blood vessel problems?
- do you have or have you ever had thrombosis (blood clots)?

- have you recently had unexpected vaginal bleeding?
- do you have or have you ever had liver disease?
- do you have uterine fibroids?

Careful examinations should be performed, by your doctor, at regular intervals during therapy. have you had heart failure, kidney problems or severe hypertension?

Also tell your doctor if:

you have or have ever had too much cholesterol or other fatty substances in the blood.
you have been treated with other sex hormones recently.

Tell your doctor if you are or think you are allergic to any of the components of the gel. The ingredients are listed at the end of this leaflet.

Your doctor will conduct a complete gynaecological examination before commencement with Oestradiol.

Breast cancer

Before starting with hormone replacement therapy (HT) you have to inform your doctor of your personal and family medical history. You will get a general and gynaecological examination. You will also get periodic check-ups, especially examinations of the breasts. Every woman is at risk of getting breast cancer, whether or not she takes HT. Breast cancer has been found slightly more often in women using HT than in women of the same age who have never used HT.

It is not known whether Oestradiol is associated with the same higher chance of having breast cancer diagnosed as other hormone replacement therapies.

Nevertheless, if you are concerned about the risk of breast cancer, discuss the risk compared to the benefits of treatment with your doctor.

Stroke:

There may be an increased risk of stroke when using this product.

Ovarian Cancer:

There is an increased risk of ovarian cancer for women taking an oestrogen only product like Oestradiol.

Women who still have a uterus must take both oestrogen and progestogen as part of HT. This is because oestrogen stimulates the growth of the lining of the uterus (called the endometrium). Before menopause this lining is shed during your period through the action of a natural progestogen.

After menopause, taking oestrogen on its own as HT may lead to irregular bleeding and a disorder of the uterus lining called endometrial hyperplasia, which can become endometrial cancer. Progestogens help protect the lining of the uterus from developing this disorder. Also, clinical studies on similar products showed a possible increased risk of cardiovascular problems in the first year of use and no benefit thereafter.

Thrombosis (blood clots)

All women have a very small chance of having a blood clot in the veins of the leg, lung or other parts of the body whether or not they take HT. Using some forms of HT may slightly increase this small chance. Whether or not Oestradiol may increase the chance of having a blood clot is not known.

You are more likely to have a blood clot (whether or not you use HT) if:

- you are very overweight
- you have had a blood clot in the veins of your legs or in your lungs before 3. blood clots run in your family
- you have systemic lupus erythematosus (a disease of your immune system)
- you are unable to move for long periods, for example after a long illness or major operation
- may be also if you have varicose veins.

If any of these apply to you, you should talk to your doctor about whether you should use Oestradiol.

If you get a blood clot while you are using Oestradiol you should stop taking it immediately and contact your doctor.

Warning signs to look out for are:

- unusual pains or swelling of your legs
- pain in your chest or sudden shortness of breath

Other medicines may influence the effects of Oestradiol, or Oestradiol may affect other medicines.

You must tell your doctor or pharmacist if you are taking (or intend to take) other medicines such as:-

barbiturates, carbamazepine and hydantoins (medicines for epilepsy or sleeplessness); rifampicin (medicine for bacterial infections); 4. meprobamate and phenylbutazone. These drugs may reduce the effects of Oestradiol. Oestradiol may also reduce the effectiveness of other medicines such as some oral hypoglycaemics (medicines which lower blood sugar), antihypertensives (medicines which lower blood pressure) and some anticoagulants (medicines which "thin" the blood). Let your pharmacist or doctor know if you are a diabetic, or are being treated for blood clotting or high blood pressure.

If you are pregnant or breast-feeding, or think you may be pregnant, do not use Oestradiol.

Yearly medical checks are recommended. Additionally, the doctor may check with you on how the treatment is progressing every six months or so.

Using Oestradiol

Apply Oestradiol as directed by your doctor. You should also read the instructions on the label of your medicine. If you are not sure how to use Oestradiol ask your doctor or pharmacist.

How and when to apply Oestradiol.

Oestradiol should not be applied on the breasts, face or irritated skin.

Avoid contact with eyes, if Oestradiol does get into your eyes, wash out thoroughly with water. Wash hands thoroughly immediately after application.

In clinical trials the use of Oestradiol has infrequently caused irritation of the skin. The chance of skin reactions can be further decreased by changing the area of application daily (e.g. left and right side on alternate days).

Oestradiol is used either cyclically or continuously, in individually adjusted doses. Most patients can start with a 1.0 mg oestradiol dose daily.

If you have not had a hysterectomy, your doctor will probably prescribe a progestogen for cyclical use, to help prevent overgrowth of the tissues lining your womb.

With cyclic progestogen use a withdrawal bleed resembling normal menstruation will occur after the progestogen treatment. Unexpected or prolonged uterine bleeding during therapy should be reported to your doctor and its cause clarified.

What to do if you miss a dose.

If you forget to apply the hormone do so as soon as you remember, unless you are more than twelve hours late. If you are more than twelve hours late, do not apply the missed dose and just carry on with the next dose as normal.

While you are using Oestradiol

Ability to drive or operate machinery. As far as is known, Oestradiol has no effect on alertness and concentration.

If you are unsure of any of the aspects of this product, please discuss with your doctor or pharmacist.

Side Effects of Oestradiol

Side effects, which may or may not be related to Oestradiol are most common in the first months of the treatment. They are usually mild leading only seldom to discontinuation of the treatment.

Common (more than 1/100): tension in the breasts, headache, fatigue, nausea, dizziness, palpitations, oedema, weight increase, unscheduled or breakthrough bleedings.

Uncommon (less than 1/100): skeletal pain, itching, muscle pain nervousness, depression

Tell your doctor if spotting occurs, or if any side-effects become troublesome or continue. It is also important to tell your doctor or pharmacist if you experience any other unusual or unexpected symptoms during treatment with Oestradiol.

Seek advice before using other medications to deal with any side affects you may have.

You should stop using Oestradiol if you experience any signs of thrombosis (headache or pain elsewhere in your body, dizziness, fainting, disturbances in vision, swollen ankles), or jaundice (yellowing of the eyes or skin).

Pregnancy

If you are pregnant or breast-feeding, or think you may be pregnant, do not use Oestradiol.

Overdose

If someone has taken or used several sachets at once, there is no need for great concern.

However, you should consult a doctor. Symptoms that may arise are nausea and vomiting.

Vaginal bleeding may occur after a few days.

After Using Oestradiol

Storage

Keep your Oestradiol gel in the original container in a safe place out of the reach of children.

Store below 25 degrees away from direct sunlight

Disposal

Return any unused medicine to your pharmacist.