oestrogel® 0,06%

Estradiol – Gel for cutaneous application in tube

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The active substance is: 17-ß estradiol.
The other constituents are: carbomer, trolamine, ethanol, purified water.
One graduated dose corresponds to 2.5 g of gel, the equivalent of 1.5 mg of oestradiol.

Marketing authorisation holder:
Laboratoires Besins International
13, rue Périer. 92120 Montrouge (France)

Manufacturer:
Besins Manufacturing Belgium
Groot-Bijgaardenstraat, 128. 1620 Drogenbos (Belgium).

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13, rue Périer. 92120 Montrouge (France)

1. WHAT IS OESTROGEL® AND WHAT IT IS USED FOR ?

Gel for cutaneous application, tube of 80 g.
ATC classification: G03CA03
OESTROGENS - (G: genital-urinary system and sex hormones).
This medicine contains a natural oestrogen.
It is prescribed:
- for the treatment of problems due to a deficiency in oestrogens linked to the menopause. It is hormone replacement therapy or HRT.
- for the prevention of post-menopausal osteoporosis for women with an increased risk of fracture and showing either an intolerance or a contraindication to other treatments employed in the prevention of osteoporosis. The choice of this treatment should be discussed with your doctor.
Experience of this treatment in women above 65 years of age is limited.

2. WARNING!

WHEN SHOULD OESTROGEL® NOT BE USED?
OESTROGEL® SHOULD NO BE USED in the following cases:
- history or a current venous or arterial thrombo-embolic diseases (phlebitis, pulmonary embolia, angina pectoris, myocardial infarction, cerebral vascular incidents);
- breast cancer, uterine or any other oestrogen-dependent cancer;
- endometrial hyperplasia (excessive development of the uterine mucous membrane);
- undiagnosed vaginal bleeding;
- certain liver illnesses;
- known allergies to one of its constituents;
- porphyria (*hereditary disease*).

WARNINGS AND SPECIAL PRECAUTIONS FOR USE:

A medical examination is required before and periodically in the course of treatment. At regular intervals (at least once a year), your doctor will invite you to discuss the benefits and risks associated with hormone replacement therapy in order to evaluate whether you should continue or stop your treatment.

Your doctor will carry out regular clinical examination of the breasts, especially in cases involving history of breast cancer in your family or if you have cysts or lumps in your breasts. Your doctor could also decide to prescribe a mammography. Inform your doctor if you notice a modification in your breasts during treatment.

Women who use a hormone replacement therapy have an increased risk of developing a thrombo-embolic disease, a breast cancer or uterine cancer and perhaps a cardiovascular incident or a cerebral vascular problem.

With women who still have their uterus, a progestagen treatment will be added during at least 12 days in the cycle.

Inform your doctor of any disease occurring during treatment. In the following situations, treatment of the menopause is not contraindicated but requires special attention: hypertension, diabetes, endometriosis (an infection characterised by the presence of uterine mucous outside the uterus), uterine fibroma, hepatic or biliary problems, epilepsy, migraines or severe head-aches, renal or cardiac insufficiency, asthma, lupus (*a severe illness attacking the skin in particular*), otospongiosis (*an infection of the ear leading to a loss of hearing*).

Contact your doctor immediately in the case of the appearance of one of the following:
- allergic reactions (breathing difficulties, thoracic oppression, generalized eruption such as urticaria, itching);
- jaundice (of the eyes and skin);
- significant increase in arterial tension;
- significant increase in blood pressure;
- unusual pain in the legs, weakness in the limbs;
- chest pains, irregular pulse, sudden breathlessness;
- loss of consciousness, confusion, unusually severe headaches, vertigo, visual problems, slowness or loss of speech;
- pregnancy;
- lumps in the breasts.

Inform your doctor if you have to remain in bed or if you have to undergo a surgical operation.
If the symptoms of oestrogen deficiency linked to the menopause persist in spite of the treatment, tell your doctor.
If abundant bleeding occurs, consult your doctor.

Ovarian Cancer
Ovarian cancer is much rarer than breast cancer. Epidemiological evidence from a large meta-analysis suggests a slightly increased risk in women taking oestrogen-only or combined oestrogen-progestagen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping. Some other studies, including the Women's Health Initiative trial, suggest that use of combined HRTs may be associated with a similar or slightly smaller risk.

Breast Cancer
The overall evidence shows an increased risk of breast cancer in women taking combined oestrogen-progestagen or oestrogen-only HRT, that is dependent on the duration of taking HRT.
The Women's Health Initiative study (WHI) trial found no increase in the risk of breast cancer in hysterectomised women using oestrogen-only HRT.
Observational studies have mostly reported a small increase in risk of having breast cancer diagnosed that is substantially lower than that found in users of oestrogen-progestagen combinations.
Results from a large meta-analysis showed that after stopping treatment, the excess risk will decrease with time and the time needed to return to baseline depends on the duration of prior HRT use. When HRT was taken for more than 5 years, the risk may persist for 10 years or more.

MEDICINAL INTERACTIONS AND OTHER INTERACTIONS:
Tell your doctor or pharmacist if you take or have recently taken another medicines, especially an anticonvulsant, anti-tuberculosis or treatment for AIDS such as: carbamazepine, oxcarbazepine, phenobarbital, phenytoine, rifabutine, rifampicin, ritonavir, nelfinavir, nevirapine, efavirenz or preparations based on plants containing St.-John's-wort (*Hypericum perforatum*), even when it is a medicine obtained without a prescription.

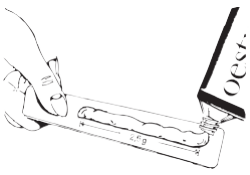
PREGNANCY – BREAST-FEEDING:
This medicine should not be taken during pregnancy or when breast-feeding.
If you discover that you are pregnant when taking this medicine, stop the treatment and consult your doctor.
Discovery of pregnancy exposed accidentally to this medicine does not justify a termination (of pregnancy).

Ask your doctor's or pharmacist's advice before taking another medicine.

3. HOW TO USE OESTROGEL® ?

DOSAGE:
The oestradiol gel is presented in a tube.
Each graduated measure delivers 2.5 g of gel, containing 1.5 mg of oestradiol.
The average dose is 1 graduated measure per day, during 24 to 28 days per month.
Your doctor will prescribe OESTROGEL® according to a scheme adapted to your case.
Bleeding resembling menstrual bleeding can occur during the period of discontinuation. This bleeding is normal and is not abundant.
If irregular or over-abundant bleeding occurs, consult your doctor.
If you have the impression the effect of OESTROGEL® is too strong or too weak, consult your doctor or pharmacist.
Estrogen with or without progestogens should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual women.

ADMINISTRATION METHOD AND ROUTE:
Transdermal route.
Application of the gel is made over a large surface of clean skin (on the arms, upper part of the bottom, lower part of the abdomen, lumbar region, upper part of the thighs, etc.).



The gel should not be applied to the breasts or the mucous membranes.
A massage is usefulness but it is recommended to let it dry for about 2 minutes first before putting on clothing. The gel does not leave marks.
It is recommended to wash hands after applying the gel.

FREQUENCY AND MOMENT AT WHICH THE MEDICINE SHOULD BE ADMINISTERED:
The application can take place either in the evening or in the morning.

DURATION OF TREATMENT:
According to your doctor's indications.

STEPS TO TAKE IN THE CASE OF OVERDOSING:
The signs of an overdose are usually a feeling of pain in the breasts, abdominal swelling, flatulence, irritability. No specific treatment is required. These signs disappear when the dose is reduced.
If these symptoms persist, consult your doctor

STEPS TO TAKE IN THE CASE WHERE ONE OR MORE DOSES HAVE BEEN OMITTED:
If you forget to use OESTROGEL®: if you have forgotten to apply the gel on the planned day, do it as quickly as possible and return to the therapeutic schedule as initially intended.
Do not take a double dose to compensate for the single dose you have forgotten to take.
If you have not been treated for several days in a row, irregular bleeding may occur.
If you have any doubts, consult your doctor.

RISK OF WITHDRAWAL SYMPTOMS
When the treatment is ended, signs of a deficit in oestrogen linked to the menopause could reappear.

4. POSSIBLE SIDE EFFECTS:

LIKE ALL ACTIVE PRODUCTS, THIS MEDICINE CAN, IN CERTAIN INDIVIDUALS, PRODUCE SOME MORE OR LESS UNCOMFORTABLE EFFECTS:
Frequently observed during a hormonal treatment of the menopause:
- breast tension;
- genital bleedings;
- abdominal pain and swelling;
- nausea;
- headaches;
- painful periods;
- vaginal discharge.

Rarely observed:
- vomiting;
- changes in the hepatic function (*liver*), an icterus (*jaundice*), an infection of the biliary vesicle;
- libido disorders;
- skin disorders.

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If you notice undesirable side-effects not mentioned in these instructions, please inform your doctor or pharmacist

Ovarian Cancer

Use of oestrogen-only combined oestrogen-progestagen HRT has been associated with a slightly increased risk of having ovarian cancer diagnosed.

A meta-analysis from 52 epidemiological studies reported an increased risk of ovarian cancer in women currently using HRT compared to women who have never used HRT (RR 1.43, 95% CI 1.31-1.56). For women aged 50 to 54 years taking 5 years of HRT, this results in about 1 extra case per 2000 users. 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.

5. HOW TO STORE OESTROGEL® ?

KEEP OUT OF THE REACH OR SIGHT OF CHILDREN EVEN AFTER USE.

There are no particular storage recommendations.

Do not exceed the use-by date noted on the external packaging.

In the case of visible signs of deterioration, return the medicine to your pharmacist.

It can only be supplied by your pharmacist upon presentation of your prescription.

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