oestrogel®

Tube containing 80 g

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 .

ACTIVE INGREDIENT

17β-Estradiol .....60 mg
Excipient (carbomer, trolamine, ethanol, purified water q.s.f).....100 g

PHARMACODYNAMICS

Natural estrogen therapy by the transcutaneous route has the following advantages:
- the use of the natural estrogen secreted by the ovary, namely 17beta-estradiol;
- avoid the first pass effect through the liver which results in the synthesis of angiotensinogen, very low density lipoproteins and certain clotting factors which it is thought produce cardiovascular, thrombo-embolic and metabolic side-effects.

Controlled study conducted with transdermal forms of estrogens have shown that the effect on prevention of bone loss varies depending on the patient but is proportional to the dose of estrogens delivered.
With this gel, at the dose of 2.5g of gel per day, 21 days out of 28, the effect is obtained in around 89% of the women treated (against 45% under placebo).

PHARMACOKINETICS

Percutaneous absorption amounts to approximately 10% of the dose applied: one ruler (2.5g of gel) corresponds to the absorption of 150ug of estradiol.
There is temporary storage in the horny layer of the epidermis. From this site, there is slow diffusion into the systemic circulation via the capillaries in the dermis.
The plasma concentration of 17beta estradiol obtained in menopausal women after the administration of one ruler (2.5g of gel) per day is on average 80 pg/ml, with an estrone/estradiol ratio similar to of women in genital activity period.

INDICATIONS

OESTROGEL is indicated in estrogen deficiency, following the decrease in ovarian activity:
-vasomotor disorders, hot flushes.
-vaginal atrophy and dryness which may disrupt sexual intercourse.

ROUTE OF ADMINISTRATION: Transdermal

INTERACTION WITH OTHER MEDICATIONS

* Enzyme inducing drugs: anti-convulsants (carbamazepine, phenobarbital, phenytoin, primidone), barbiturates, griseofulvin, rifabutin, rifampicin : risk of reduction in the efficacy of the estrogen. Careful clinical monitoring and possible adjustment of the dose of estrogen may be required.

PREGNANCY AND LACTATION

Pregnancy:
This medicinal product has no indication during pregnancy. Clinically speaking, the results of numerous epidemiological studies to date have not shown any risk of malformation at the start of pregnancy with estrogens administered alone or in association.

Consequently, the late diagnosis of pregnancy during exposure to estrogens (or estro-progestogens) does not necessitate its interruption.

Lactation: not applicable.

CONTRAINDICATIONS

This drug should not be prescribed in the following situations:
- current venous thromboembolic disease,
- recent arterial thrombotic disease (in particular coronary or cerebral vascular accidents),
- known or suspected malignant estrogen-dependant disease (for example breast or uterine cancer),
- undiagnosed vaginal bleeding,
- severe hepatic disease
- hypersensitivity to any of the components of the gel,

Although in the short term the blood clotting factors are not altered due to this treatment, it should usually be avoided in the following situations (as a precaution and in the absence of sufficient epidemiological data):

- embolic cardiac disease.
- recent and documented medical history of venous thromboembolic disease.

DOSE

For percutaneous application only 2.5 gm (One measure) every day for 21 to 25 days per calendar month or according to doctor's prescription

DIRECTION FOR USE

You have been provided with a tube and white plastic ruler with central groove:
- The tube should be opened by unscrewing the cap, turning it upside-down and pressing the pointed end firmly into the tube with a twisting movement in order to break the metal seal. The latter must be entirely opened in order to allow the gel to be pressed out of the tube correctly (in a cylinder of the diameter of a pencil).
- To measure your daily dose, the central groove of the plastic ruler indicates the length and width of an average dose of gel (2.5g). Press the bottom of the tube so that the cylinder of gel fills the length of the groove. The tube used in this manner will give you 30 "doses". All the gel must be removed from the ruler with the fingers.

OESTROGEL must be applied:
- by the patient herself
- either morning or evening, preferably after washing.

Spread out over the largest possible area of skin, applied to arms, forearms and shoulders, for example, but avoiding the breasts, vulvar and vaginal mucosa.

Leave to dry two minutes (the time it takes to brush one's teeth) before covering with clothing. Should the skin remain tacky after two minutes, this means that the area of application was insufficient, remember to spread the gel over a larger area next time.

OESTROGEL does not stain.
OESTROGEL should not be swallowed.

SIDE EFFECTS

Most of the following severe accidents reported were seen mainly with artificial estrogens and after oral use. Such incidents were very rare. However, out of prudence, it would be preferable to stop treatment if one of the following phenomena develops:
- cardiovascular or thrombo-embolic accident,
- cholestatic jaundice,

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BESINS HEALTHCARE

5006380 PIL OESTROGEL 80G CTU MYS

ITEM NUMBER		CHECKLIST		FONTS
NAME	5006380V.AI	N° BESINS	NA	
REG SITE	5005932	ZONE D'EMBOSSAGE LIBRE	NA	
TYPE	LEAFLET	LISIBILITÉ CODE BARRE	NA	
DWG NR	582 V2	CONFORMITÉ BRAILLE	NA	
# COLORS	501	POSITION SPOT	NA	
COUNTRY	MYS	ROUTING	NA	**APPROVALS**
DATE	25-october-2024	DATE	NA	Regulatory Approval
ROUTING	2			

COLORS (QC tolerance: +/- 1 PMS LEVEL)

	NAME	OPACITY		
#1	PANTONE Process Black U	■	VARNISH	
			BRAILLE	
			DIECUT	■

Marketing Approval

Technical Approval

- benign mastopathy, uterine tumour, (for example : increase in the volume of a fibroma),
- hepatic adenoma : this can give rise to intra-abdominal haemorrhage,
- galactorrhoea : if this symptom develops, a search should be made for a pituitary -adenoma.

More frequent but minor incidents can occur which do not usually require treatment to be stopped but the dose to be adjusted depending on whether the symptoms or signs suggest excess or insufficient estrogen:

Signs of insufficient estrogen:
- persistent hot flushes,
- simple headaches, migraines,
- dryness of the vagina
- ocular irritation due to the contact lenses.

Signs of excess estrogen:
- nausea, vomiting, abdominal cramps, flatulence,
- tension in the breasts,
- irritability,
- oedema, heaviness of the legs,
- increased secretions from the uterine cervix.

Other undesirable effects:
- metrorrhagia, which should suggest a search for a subjacent disease, in particular endometriosis,
- exacerbation of epilepsy,
- chloasma or melasma which can be persistent.

WARNING

- In some patients the absorption of estradiol is insufficient by the transcutaneous route. In such cases, if the symptoms related to estrogen deficiency persist, it is recommended to use a higher dose, another form or another route of administration of the drug.

- As the risk of endometrial cancer increases after prolonged and isolated use of estrogens, it is highly recommended to associate a progestogen during at least 12 days of each monthly cycle of treatment.

Before starting or changing hormone replacement therapy of the menopause (HRT), it is essential to carry out a complete clinical and gynaecological examination (family past history should also be collected), taking into account the contra-indications and special warnings.
Throughout treatment, regular examinations should be made, their nature and frequency adapted to each patient. An examination and/or mammography of the breasts will also be conducted if necessary and depending on the patient.
The results of a meta-analysis of 51 epidemiological studies showed that the probability of diagnosing a breast cancer increases slightly or moderately in women presently or recently treated with HRT.
This increase in risk may be due to earlier diagnosis, to the effects of HRT itself, or to the association of these two factors.

This risk increases with the duration of treatment and progressively returns to normal during the 5 years following suspension of HRT.

In these women, the type of breast cancer observed is often localized and therefore of better prognosis than that in women not treated with HRT.

Between the ages of 50 and 70, around 45 women out of 1 000 not using HRT will present a breast cancer; this percentage increases with age. Within this age range in women using HRT for 5 to 15 years, the supplementary number of breast cancers diagnosed is of around 2 to 12 cases for 1000 women using HRT.

- Control case studies have shown that hormone replacement therapy (HRT) is associated with an increased risk of venous thrombo-embolic accident, from 1 case per 10 000 women in the general population to 2- 3 cases per year for 10 000 women treated with HRT.

PRECAUTION

- A medical examination should be carried out before and periodically during the course of estrogen therapy. Special attention should be paid to the breasts, uterus, blood pressure and body weight.

- Hormone replacement therapy should be instituted only after assessment of the cardiovascular and /or metabolic status of the patient, and the patient should be carefully monitored in the following situations:
  - ischaemic cerebral accident due to atherosclerosis,
  - cerebral haemorrhage,
  - retinal vein occlusion,
  - obesity, because of the risk of venous thrombosis,
  - confinement to bed and surgery 9it is advisable to stop treatmtnt one month before planned surgery).
  - complicated diabetes (especially in the presence of a microangiopathy).
  - high blood pressure.

- The benefits and risks of treatment should be evaluated and monitored carefully in patients with the following conditions:
  - endometriosis,
  - endometrial hyperplasia, uterine fibroma,
  - benign tumours of the skin,
  - disseminated lupus erythematosis,
  - prolactin-secreting pituitary tumour,
  - porphyria

- Patients with the following conditions should also be carefully monitored:
  - recurrent cholestasis or relapsing pruritus during pregnancy, renal failure, epilepsy, asthma, family history of breast cancer, liver disease or otospongiosis.

TREATMENT OF OVERDOSE

The effects of overdosage are usually a sensation of tension in the breasts, abdominal and pelvic swelling, anxiety, irritability (see posologyand method of administration). These signs disappear when the treatment is stopped or when the dose is reduced.

PACKING: 80 g tube.

STORAGE: dry and cool place. Store below 30°C. Protect from light.

MANUFACTURER:
Besins Manufacturing Belgium
128 Groot-Bijgaardenstraat, 1620 Belgium

PRODUCT REGISTRATION HOLDER:
EP PLUS GROUP SDN. BHD.
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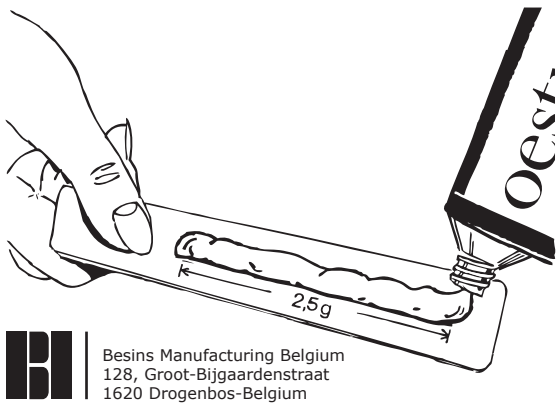
DATE OF REVISION: 25/10/2024



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