



BESINS
HEALTHCARE

5005868 PIL OESTRODOSE R 80G MYS

ITEM NUMBER		CHECKLIST	FONTS
NAME	5005868	N° BESINS	XX Arial narrow regular
REPLACE		ZONE D'EMBOSSAGE LIBRE	XX Arial narrow bold
TYPE	LEAFLET	LISIBILITÉ CODE BARRE	XX Arial narrow italic
DWG NR	L : 490 x H : 435 mm	CONFORMITÉ BRAILLE	XX
# COLORS	501	POSITION SPOT	XX
COUNTRY	MYS	ROUTING	XX
DATE	13-May-2025	DATE	XX
ROUTING	5		
COLORS (QC tolerance: +/- 1 PMS LEVEL)			
	NAME	OPACITY	Marketing Approval
#1	PANTONE PROCESS BLACK C		VARNISH
			BRAILLE
			DIECUT
			Technical Approval

Oestrodose®

Metered dose pump

For topical administration

Active Ingredient

This canister delivers 64 metered doses.
Each metered dose (1.25g gel) contains 0.75mg 17β-estradiol.

Other ingredients: Carbomer, 95% v/v ethanol, triethanolamine and purified water.

Product Description: Container with pump and cap containing a colourless, transparent gel with an alcoholic odour.

Mode of action:

General estrogen therapy via the percutaneous route:
Uses the natural estrogen secreted by the ovary: 17β- estradiol
Pharmacology:

- General estrogen therapy by the percutaneous route, with the following advantages: Use of the estrogen naturally secreted by the ovary, named estradiol 17β;
- Avoids the effects of first passage through the liver, which increases angiotensinogen synthesis, VLDL lipoproteins and certain clotting factors considered to favour the development of cardiovascular,thromboembolic and metabolic side-effects.

Pharmacokinetic properties:

Percutaneous absorption equal to around 10% of the dose applied: one metered dose delivered 75 µg of estradiol. There is a transitory stockage in the corneal of the epidermis. There is slow diffusion into the general circulation via the dermic capillary bed. The plasma level of 17β-estradiol obtained in menopausal women receiving 2 measures per day of Oestrodose is on average 80 pg/ml. The estrone/ estradiol ratio is similar to that seen in non-menopausal genitally active women.

Indications:

Indicated in estrogen deficiency following the decrease in ovarian activity:

- Vasomotor disorders, hot flushes
- Vaginal atrophy and dryness which may disrupt sexual intercourse

Recommended Dose:

Posology and method of administration:
OESTRODOSE is presented in bottles supplied with a metered dose pump.
Each pressure dose delivers 1.25 gm of gel, containing 0.75 mg of estradiol
The mean dose is 2.5 gm of gel per day, i.e. 2 pressure doses for a period of 24 to 28 days.
The posology may be readjusted after 2 or 3 cycles of treatment depending on the clinical symptoms.

A reduction in dose if there are symptoms of excessive estrogen such as mammary swelling, swelling of the abdomen and pelvis, anxiety, nervousness or aggressiveness.

An increase in the dose if there are signs of estrogen insufficiency such as persistent hot flushes, dryness of the vagina, headaches and sleep disturbances, fatigue and depression.

A progestogen must be associated with the present treatment for at least 12 days during the monthly cycle. There may be withdrawal bleeding after the end of each treatment period.
Maximum dose daily is 5.0gm of gel or not exceeding 4 pressure doses a day.

Mode of Administration:

To apply Oestrodose remove the cap to reveal the plunger. This plunger when depressed, dispenses the correct amount of gel. Make sure that your hands and skin of the area of application are clean, dry and unbroken.

Hold the Oestrodose pump pack in one hand and place the other hand under the spout, ready to collect the gel.

Depress the plunger firmly and one precise measure of Oestrodose will be dispensed. Apply one or two measures of Oestrodose to the skin of the arms and shoulders and spread evenly. Do not apply on or near the breasts, or near genital area.

Cover the spout using the attached stopper and don't forget to replace the cap.

Note: If your doctor has prescribed 2 measures of gel, you will need to spread one measure over each arm and shoulder. At the standard daily dose, the Oestrodose pump-pack will last for four weeks.

Contraindications:

Malignant tumors of the breast or uterus, pituitary tumors, severe hepatic, renal or cardiac disease, porphyria, active deep vein thrombosis, thromboembolic disorders or a confirmed history of these conditions. Undiagnosed vaginal bleeding

Precautions:

A complete medical and family history should be obtained prior to the initiation of any estrogen therapy.

Before commencing any therapy, the patient should have a complete physical and gynaecological examination including blood pressure, breasts, abdomen and pelvic organs and endometrial assessment where necessary. This should be repeated at regular intervals.

Patients with a uterus should be monitored at least annually for signs of endometrial hyperplasia or endometrial cancer.

Women who have not had their uterus removed. The addition of 10 or more days of Progesterone starting from the 8th-10th day of Oestrodose therapy is to protect against hyperplastic changes of the endometrium.

Use this medicine CAREFULLY in the following cases:

Epilepsy, asthma, past family history of breast cancer, liver function disorders, severe hypertension.

Use in children is not recommended.

Interaction with Other Medicaments

Treatment with surface-active agents, or other drugs which alter barrier structure or function, could remove drug bound to the skin, altering transdermal flux.

Therefore patients should avoid the use of strong skin cleansers and detergents, skin care pro-

ducts of high alcohol content and keratolytics. The use of any concomitant skin medication which alters skin production should be avoided.

Drug which induce hepatic enzymes such as barbiturates, hydantoin, carbamazepine, meprobamate, phenylbutazone or rifampicin which can affect the action of estrogen.

Whether such interference occurs when estrogens are administered by the percutaneous route is unknown.

Pregnancy & Lactation

Use in pregnancy: Estrogen should not be used during pregnancy

Use in lactation: As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

Undesirable effects

Nausea, headache, breast tension, heavy legs, intermenstrual bleeding, ocular irritation, worsening of the secretion of cervical discharge. Very rare cases: skin irritation, reddening of the skin or mild and transient erythema at the side of application.

Overdose and treatment

The effects of overdosage are generally a sensation of tension in the breasts or abdominal swelling. The management of overdosage is reduced the dosage to half or divide the dose to every other day.

Storage conditions:

Store below 30°C

Do not expose to excessive heat, do not puncture, do not throw in fire even when empty.

Do not exceed the expiry date labeled on the bottle.

Shelf life: Please refer to the outer label

Packaging: 80gm of gel in a PE/Polypropylene bottle supplied with metered dose pump.

Manufactured by:

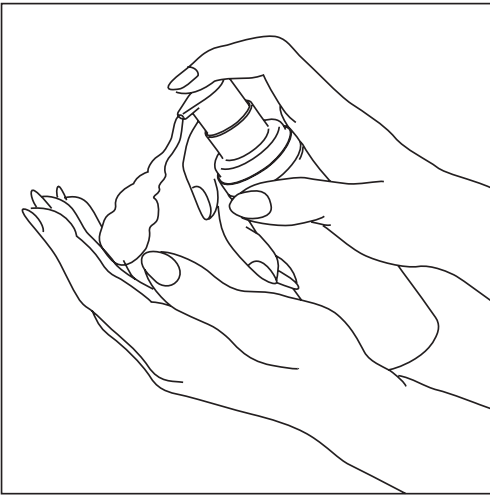
Laboratoires Besins International
13 rue Perier, Montrouge,92120, France

Product Registration Holder:

EP PLUS GROUP SDN. BHD.
Block C-3-1, Plaza Mont Kiara,
No. 2, Jalan Kiara, Mont Kiara,
50480 Kuala Lumpur, Malaysia

Date of Revision of Package Insert: May 2025.

Product Instructions

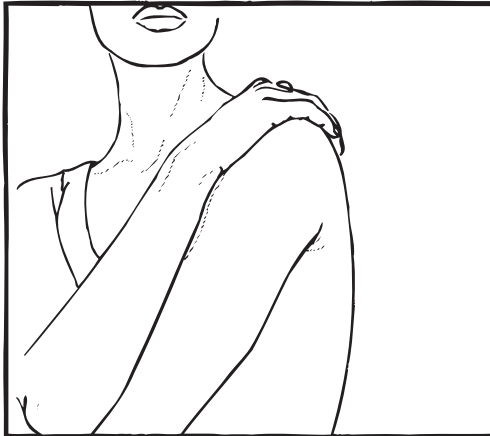


- Remove the cap from the canister.
- Hold the Oestrogel Pump Pack in one hand and place your other hand under the spout, ready to collect the gel.
- Push the pump down firmly and collect it with your other hand to avoid spillage.

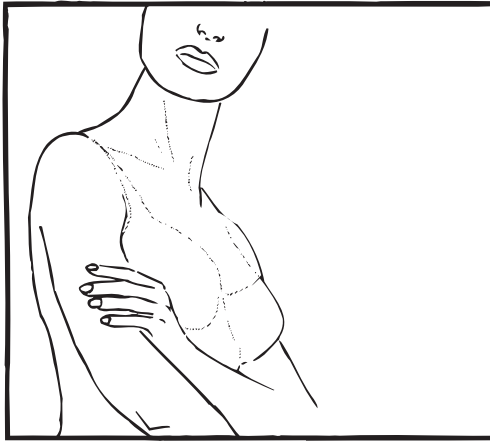


- Whenever it uses, press the pump one or two times to see if it is pumping well.
- The gel emitted at the first pump may not be fixed dose, so do not use it.
- Do not use any remaining medication after the 64th pump, as the gels may emit less than the fixed quantity

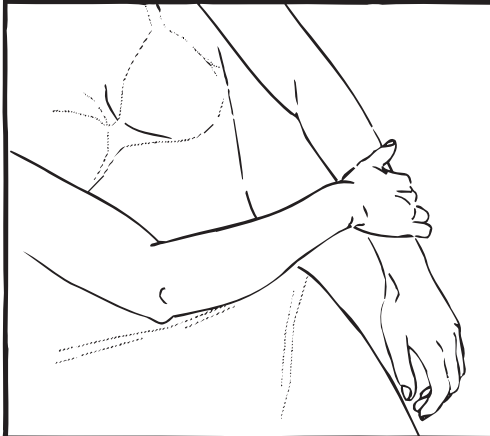
In practice



- Spread the gel on a large area of skin on abdominal, thigh, outer arm or waist except for breast and vulva.
- Single-compression volume : 0.75 mg of Estradiol (1.25g of gel)



- You don't need to massage or rub.
- Avoid direct contact with mucous membranes with agents containing alcohol solvents (ethanol).



- Dry enough for 5 minutes before putting on clothes.

