OESTRODOSE GEL®

Estradiol Hemihydrate (60mg/100g)

What is in this leaflet

What Oestrodose is used for

Oestrodose is used for general estrogen therapy that is absorbed through the skin. It contains the female hormone oestrogen.

Oestrodose is indicated for estrogen deficiency, following the decrease in ovarian activity:

- Blood vessels constriction dilation disorders, hot flushes.
- Vaginal dryness and thinning of vaginal wall which may disrupt sexual intercourse.

How Oestrodose works

Oestrodose works by replacing the oestrogen in your body.

Before you use Oestrodose

- *When you must not use it*

Do not take Oestrodose:

- If you are allergic to estradiol or any of the other ingredients of this medicine.
- If you are pregnant.
- If you have malignant tumors of the breast or uterus, pituitary tumors.
- If you have severe liver, kidney or heart disease, porphyria (a group of diseases in which substances called porphyrins build up, affecting the skin or nervous system), blood circulation disorders such as blood clots in the veins of the legs or the lungs or a confirmed history of these conditions.
- If you have undiagnosed vaginal bleeding.

A complete medical and family history should be obtained prior to starting any estrogen therapy.

Before commencing therapy, you 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.

People with a uterus should be monitored at least annually for signs of thickening of uterus lining or endometrial cancer.

Women who have not had their uterus removed. The addition of 10 or more days of progesterone starting from the 8^{th} to 10^{th} day of Oestrodose therapy is to protect against thickening changes of the endometrium.

- *Before you start to use it*

Please inform your doctor or pharmacist if you are having any medical conditions .

- *Taking other medicines*

Please inform your doctor or pharmacist if you are taking or have recently taken or might take any other medicine.
Barbiturates, hydantoin and carbamazepine: to control seizures.
meprobamate: to treat symptoms of anxiety and nervousness.
phenylbutazone: short-term treatment of pain and fever.
rifampicin: antibiotic used to treat bacterial infections.

How to use Oestrodose

- *How much to use*

Oestrodose is presented in bottles supplied with a metered dose pump. Each pressure dose delivers 1.25gm of gel, containing 0.75mg of estradiol. The mean dose is 2.5gm of gel per day, i.e. 2 pressure doses for a period of 24 to 28 days.

The dosage 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 breast 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 5gm of gel or not exceeding 4 pressure doses a day.

- *When to use it*

Always take this medicine exactly as your doctor or pharmacist has advised. Please consult your doctor or pharmacist if you are unsure.

- *How long to use it*

Continue taking Oestrodose for as long as your doctor recommends.

- *Directions to use*

To apply Oestrodose remove the cap to reveal the plunger (figure 1). 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 (figure 2).
Depress the plunger firmly and one precise measure of Oestrodose will be dispensed (figure 3).
Apply one or two measures of Oestrodose to the skin of the arms and shoulders and spread evenly (Figure 4).
Cover the spout using the attached stopper (figure 5) and don't forget to replace the cap (figure 6).

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.

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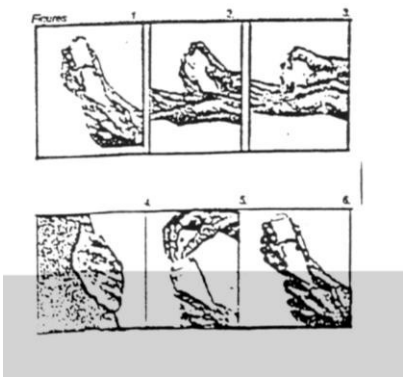

- *If you forget to use it*

Do not use a double dose the next day to make up for a missed dose on the previous day.

- *If you use too much (overdose)*

The effects of overdosage are generally a sensation of tension in the breasts or abdominal swelling. These signs will generally disappear if you reduce the amount of gel applied.

If you have any further questions on the use of this medicine, please consult your doctor or pharmacist.

While you are using it

- *Things you must do*

Once you have started on Oestrodose you should see your doctor for regular check-ups. At these check-ups, discuss with your doctor the benefits and risks of continuing with Oestrodose.

- *Things you must not do*

Avoid using strong skin cleansers and detergents, skin care products of high alcohol content and peeling agent.

Use in pregnancy:
Estrogen should not be used during pregnancy

Use in breastfeeding:
As a general principle, the usage of any medicines to nursing mothers should be done only when clearly necessary since many medicines are found in human milk

- *Things to be careful of*

Use this medicine CAREFULLY in the following cases:
Fits, asthma, past family history of breast cancer, liver function disorders, severe high blood pressure. Use in children is not recommended.

Side effects

Like all medicines, this medicine may cause side effects, although not everyone experiences them.

Oestrodose may cause nausea, headache, breast tension, heavy legs, intermenstrual bleeding, eye irritation, worsening of the secretion of cervical discharge.

Very rare cases: skin irritation, reddening of the skin or mild and transient redness at the side of application.

If you experience any side effects, please consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you may help provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03 – 7883 5550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Oestrodose

- *Storage*

Keep this medicine out of sight and reach of children.
Store below 25°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.

- *Disposal*

Do not use this medicine if you notice any visible signs of deterioration. Do not throw away any medicines via wastewater or household waste.

Please consult your pharmacist on how to dispose medicines you no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

Oestrodose gel is presented in 80gm of gel in a bottle supplied with metered dose container with a pump and cap, containing a colourless, transparent gel with an alcoholic odour.
This canister delivers 64 metered dose.

- *Ingredients*
- Active ingredient:

Estradiol Hemihydrate (Estradiol)

- Inactive ingredients:

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

- *MAL Number*:

MAL19990985AZ

Manufacturer

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Product Registration Holder

EP Plus Group Sdn Bhd
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