

PREMARIN[®] VAGINAL CREAM

Conjugated estrogens (0.625 mg/g)

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- if you have or suspected to have abnormal growth which is sensitive to estrogens, such as cancer of the lining of the womb (endometrium) or excessive thickening of the womb lining (endometrial hyperplasia)
- if you have or have had a disease caused by blood clots in the arteries, such as a heart attack or stroke or vein, such as in the legs or the lungs;
- if you have or have previously had liver disease
- if you have a disorder affecting your blood clotting
- if you are allergic to estrogen or any of the ingredients found in PREMARIN VAGINAL CREAM

- abnormal growth of bone of the middle ear affecting the hearing (otosclerosis)
- porphyria (a rare blood pigment disorder)
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- endometriosis (material similar to the lining of the uterus growing outside the uterus, causing pain)
- low blood calcium levels
- underactive thyroid gland

If feasible, estrogens should be discontinued at least four to six weeks before surgery

What PREMARIN VAGINAL CREAM is used for

PREMARIN VAGINAL CREAM is used to treat

- atrophic vaginitis (thinning, drying and inflammation of the vaginal walls)
- dyspareunia (painful intercourse)
- kraurosis vulvae (a condition affecting the female external genitalia, resulting in drying, shriveling and itching of the parts)

How PREMARIN VAGINAL CREAM works

PREMARIN VAGINAL CREAM contains a mixture of natural hormones called conjugated estrogens, which are similar to the hormones produced by the ovaries before menopause. When given during or after menopause, they can help control some of the symptoms, such as vaginal itching, dryness, and burning or pain during intercourse.

Before you use PREMARIN VAGINAL CREAM

- When you must not use it

Do not use PREMARIN VAGINAL CREAM:

- if you have abnormal uterine bleeding which is not diagnosed
- if you have or have had breast cancer, or if you are suspected of having it

Pregnancy and lactation

You should stop using PREMARIN VAGINAL CREAM and tell your doctor immediately if you know or suspect you are pregnant, or if you are breast-feeding.

Do not use PREMARIN if you are breast-feeding as it can be passed to babies through breast milk, and can also decrease the quantity and quality of breast milk.

Ask your doctor or pharmacist for advice before using any medicine

- Before you start to use it

- Tell your doctor if you have:
- increased risk of developing blood clots
 - any surgery planned
 - are unable to walk for a long time
 - cancer that has spread to bone
 - hereditary angioedema (swelling of the face, lips, tongue or throat)
 - heart or kidney problems
 - a very high level of fat in your blood (triglycerides)
 - asthma
 - epilepsy (fits)
 - increased risk of developing migraine or severe headaches

PREMARIN VAGINAL CREAM is not a contraceptive. It is important that you use a reliable form of non-hormonal contraception if there is any possibility that you may still become pregnant. PREMARIN VAGINAL CREAM has been shown to weaken latex condoms. Therefore, you should not use condoms, diaphragms or cervical caps made of latex or rubber as a form of contraception while using PREMARIN VAGINAL CREAM. You should discuss alternative forms of contraception with your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking:

- herbal remedy used to treat certain types of depression (such as St. John's wort)
- medicines used for treatment of epilepsy (such as phenobarbital, phenytoin, carbamazepine and lamotrigine)
- antibiotics (such as rifampicin, erythromycin and clarithromycin)

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- antifungal medicines (such as ketoconazole and itraconazole)
- medicines used to reduce inflammation (such as dexamethasone)
- medicines used for treatment of HIV infections (such as ritonavir)
- medicines used to treat ulcers (such as cimetidine)

Grapefruit juice may also affect how well PREMARIN VAGINAL CREAM works.

How to use PREMARIN VAGINAL CREAM

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will aim to give you the lowest effective dose for the shortest time to treat your symptoms.

When estrogen is prescribed for a post-menopausal woman with a uterus, a progestin should also be considered to reduce the risk of endometrial cancer.

For treating atrophic vaginitis and kraurosis vulvae: PREMARIN VAGINAL CREAM should be used in the vagina following a cyclic regimen (daily for 21 days and then off for 7 days). Generally, the starting dose is 0.5 g. Your doctor may adjust the dose (0.5 to 2 g) depending on your response to the treatment.

For treating painful intercourse: PREMARIN VAGINAL CREAM (0.5 g) should be used in the vagina in a twice-weekly (e.g. Monday and Thursday) continuous regimen or in a cyclic regimen of 21 days of therapy followed by 7 days off therapy.

To apply the cream into the vagina, the applicator should be used as follows:

1. Remove the cap from the aluminium tube of cream and screw the nozzle end of the applicator onto the tube.
2. Gently squeeze from the bottom of the tube to force the cream into the barrel of the applicator. Depending on the dose your doctor advised you to use, fill the applicator with cream up to the appropriate dosage marking.
3. Unscrew applicator from the tube.
4. Lie on back with knees drawn up. To apply the cream, gently insert the applicator deeply into your vagina and then press the plunger downward to its original position.
5. After use, remove the empty applicator.

To clean the applicator after use, pull the plunger out from the barrel and wash both parts with mild soap and warm water. Do not boil or use hot water.

PREMARIN VAGINAL CREAM is not for use in children.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using PREMARIN VAGINAL CREAM for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Applying too much PREMARIN VAGINAL CREAM may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness, tiredness and a shorter period or lighter vaginal bleeding.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using PREMARIN VAGINAL CREAM.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PREMARIN VAGINAL CREAM to anyone else, even if they have the same symptoms or condition as you have.

- Things to be careful of

Driving and using machines

There is no study performed on the effect of PREMARIN VAGINAL CREAM on the ability to drive or operate machinery.

Side effects

Like all medicines, PREMARIN VAGINAL CREAM can cause side effects, although not everybody gets them.

Check with your doctor or pharmacist immediately if any of the following occur:

- vaginal discomfort including inflammation, vaginal thrush, painful bladder syndrome
- breast cancer, ovarian cancer, cancer of the lining of the womb, enlargement of benign mass in the liver, potentiate tumour that grows from the membranes that cover the brain and spinal cord just inside the skull

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Canada

Product Registration Holder
Pfizer (Malaysia) Sdn. Bhd.
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59200 Kuala Lumpur, Malaysia

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14/07/2025

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**PLD-PREMARIN VAGINAL
CREAM-0725**

- hives, swelling under the skin layers, serious allergic reactions
- early puberty
- intolerance to glucose, decrease in blood calcium levels
- changes in sex drive, mood disturbances, irritability, depression, memory loss
- dizziness, headache, migraine, nervousness, stroke, exacerbation of abnormal involuntary movements
- difficulty wearing contact lenses
- heart attack
- blood clot in a vein, such as in the legs or eye or the lungs
- nausea; vomiting, bloating, stomach pain, inflammation of pancreas and inflammation of the large intestine
- gallbladder disease, yellowing of the whites of the eyes or skin
- hair loss, male-pattern hair growth in women, facial pigmentation, tender red bumps under the skin
- joint pain, leg cramps
- breakthrough bleeding or spotting, changes in menstrual flow, painful periods
- burning, itching and irritation at the site of application, thick vaginal discharge
- increased size of non-cancerous tumors in the womb and excessive or abnormal thickening of the lining of the uterus
- pain in the breast, enlargement of breast, discharge from the nipples
- swelling of body parts
- changes in weight; increased fat levels, increase in blood pressure

Keep out of the reach and sight of children.

Store below 25°C.

Store in a place that is not exposed to light.

Store in light-resistant containers.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White to off-white smooth cream
Combination package: Each contains Net Wt. 14 g Aluminium tube, with a white plastic cap and with one plastic applicator calibrated in ½ g increments to a maximum of 2 g.

- Ingredients

- Active ingredient:
Estrogens, conjugated

- Inactive ingredients:
Glycerin, Water Purified, Mineral Oil, Cetyl Alcohol, Propylene Glycol Monostearate, Glyceryl Monostearate Self Emulsifying, White Wax, Phenylethyl Alcohol, Cetyl Ester Wax NF, Methyl Stearate, Nitrogen Gas, Sodium Lauryl Sulphate

- MAL number

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of PREMARIN VAGINAL CREAM

- Storage

Product Name	Registration Number
Premarin Vaginal Cream 0.625 mg/g	MAL19870655AZ

Manufacturer

PF Consumer Healthcare Canada ULC
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Saint-Laurent, Quebec H4R 1J6