

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

PREMARIN® CREAM 0,625 mg

Conjugated oestrogens

Read this leaflet carefully before you start using PREMARIN cream

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PREMARIN cream has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PREMARIN cream is and what it is used for
2. What you need to know before you use PREMARIN cream
3. How to use PREMARIN cream
4. Possible side effects
5. How to store PREMARIN cream
6. Contents of the pack and other information

1. What PREMARIN cream is and what it is used for

PREMARIN cream is a Hormone Replacement Therapy (HRT) and contains the female hormone estrogen. It is used after menopause to treat menopausal changes in and around the vagina and to treat painful sexual intercourse caused by menopausal changes of the vagina. It is also used prior to plastic surgery of the pelvis in menopausal cases.

2. What you need to know before you use PREMARIN cream

Do not use PREMARIN cream:

- if you are hypersensitive (allergic) to conjugated estrogens or any of the other ingredients of PREMARIN cream (listed in section 6)
- if you are pregnant or think you may be pregnant
- if you have undiagnosed abnormal genital bleeding
- if you have or have had breast cancer
- if you have a family history of breast cancer
- if you have a history of non-cancerous breast diseases such as atypical hyperplasia or lobular carcinoma *in situ*
- if you had any previous treatment using radiation therapy to the chest or breast
- if you currently have or have had certain cancers. Estrogens may increase the chance of getting certain types of cancers e.g. breast cancer and cancer of the uterus
- if you have had a stroke or heart attack
- if you have had blood clots in your veins or lungs
- if you have an inherited disorder that affects your blood clotting
- if you have been diagnosed with a bleeding disorder
- if you have liver problems
- if you are known to have inherited genetic changes called “BRCA1 and/or BRCA2 genes”
- if you started your menstrual periods before the age of 12 years
- if you have been treated or exposed while in your mother’s womb to a medicine called diethylstilbestrol (DES)

Warnings and precautions

Take special care with PREMARIN cream:

PREMARIN cream has been associated with an increased risk of stroke and blood clots. Should these occur or be suspected, you should stop using PREMARIN cream and contact your doctor immediately.

PREMARIN cream may increase the risk of certain types of cancers (e.g. breast cancer, endometrial cancer and ovarian cancer). If you have risk factors for developing any of these conditions, your doctor may keep you under careful observation.

PREMARIN cream and breast cancer

Breast cancer has been diagnosed slightly more often in women who use menopausal hormone therapy than in women of the same age who do not use menopausal hormone therapy. After stopping use of menopausal hormone therapy, some excess risk for breast cancer persisted after 10 years. When you are using PREMARIN cream, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any appropriate investigations.

If you are 65 years old or older, using PREMARIN cream may increase your chance of getting dementia.

Make sure your doctor knows:

- if you have problems with your gallbladder
- if you experience sudden unexplained changes in vision
- if you develop migraines or suffer from worsening migraine headaches
- if you have high levels of calcium in your blood
- if you have angioedema (swelling that occurs below the surface of the skin especially around the face, lips or tongue)
- if you suffer from water retention as this may affect other conditions you have
- if you have hypertriglyceridaemia (high levels of fatty substances in your blood), as this can lead to inflammation of the pancreas
- if you have problems with your liver
- if you have a history of jaundice (a yellowing of the skin and eyes) associated with past estrogen use or with pregnancy
- if you have excessive thickening of the lining of the womb (endometrial hyperplasia)
- if you have high blood pressure

- if you have asthma
- if you have epilepsy
- if you have diabetes mellitus
- if you have porphyria (a disorder that can cause nerve or skin problems)
- if you have lupus (an autoimmune disease that causes tiredness, joint pain, rash and fever)
- if you have a non-cancerous liver tumour
- if you have endometriosis (cells similar to the lining of the uterus growing outside the uterus, causing pain or bleeding)
- if you have low calcium levels in your blood (often causing muscle cramps)
- if you have an underactive thyroid gland
- if you develop abnormal uterine bleeding

You should stop using PREMARIN cream at least 4 to 6 weeks before undergoing surgery, or if you are unable to walk for a long time because of major surgery, injury or illness,

Hormonal contraceptives, including PREMARIN cream, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression contact your health care provider for advice.

Latex or rubber condoms, diaphragms and cervical caps may be weakened and fail when they come into contact with PREMARIN cream.

Other medicines and PREMARIN cream

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions.

PREMARIN cream may affect the action of other medicines and sometimes PREMARIN cream is affected by other medicines. These may include:

- St. John's Wort (*Hypericum perforatum*) used to treat depression
- Anti-epileptic medicines including phenobarbital, phenytoin or carbamazepine
- Immunosuppressive medicines such as dexamethasone
- Antibiotics, antifungal or antiviral medicines used to treat infection e.g. rifampicin, erythromycin, clarithromycin, ketoconazole, itraconazole and ritonavir
- Medicines used to treat ulcers or other gastrointestinal disorders such as cimetidine

PREMARIN cream can affect some laboratory test results therefore please tell your doctor you are using PREMARIN before any blood tests are taken.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

PREMARIN cream should not be used during pregnancy or breastfeeding.

The estrogen hormones in PREMARIN cream can pass into your breast milk.

Driving and using machines

No studies on the effect of ability to drive or use machines have been performed. However, the adverse effects of PREMARIN cream include dizziness, which could affect the ability to drive or use machines.

It is not always possible to predict to what extent PREMARIN cream may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PREMARIN cream affects them.

PREMARIN cream contains benzyl alcohol

This medicine contains 10 mg in each gram which is equivalent to 1 % m/m. Benzyl alcohol may cause allergic reactions.

3. How to use PREMARIN cream

Do not share medicines prescribed for you with any other person.

Always use PREMARIN cream exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PREMARIN is a cream that you place in your vagina with the applicator provided.

The usual dose of PREMARIN cream is 0,5 to 2 grams daily depending on how severe your symptoms are. Treatment should be cyclic (e.g., three weeks on and one week off) and is for short term use only. The lowest dose to control your symptoms should be used. You and your doctor should talk regularly (e.g. every three to six months) about the dose you are taking and whether you still need treatment with PREMARIN cream.

Children

PREMARIN cream should not be used in children.

How to use PREMARIN cream

Step 1. Remove cap from tube.

Step 2. Screw nozzle end of applicator onto tube (Figure A).

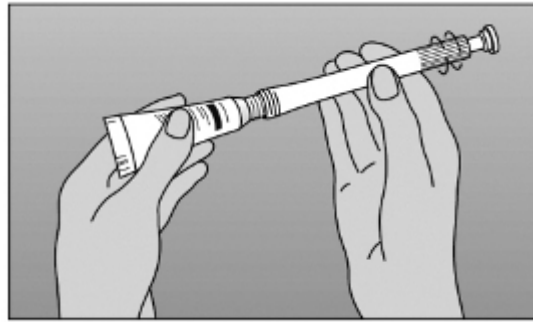


Figure A

Step 3. Gently squeeze tube from the bottom to force sufficient cream into the barrel to provide the prescribed dose. Use the marked stopping points on the applicator to measure the correct dose, as prescribed by your health care provider (Figure B).

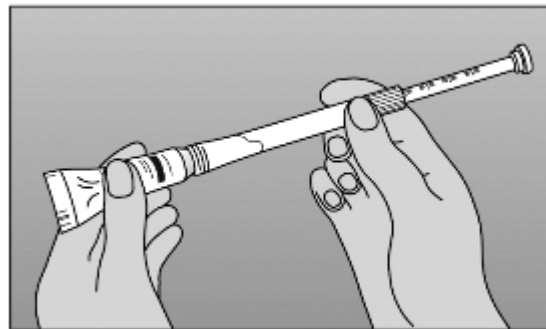


Figure B

Step 4. Unscrew applicator from tube.

Step 5. Lie on your back with knees drawn up. Gently insert applicator deeply into vagina and press plunger downward to its original position (Figure C).

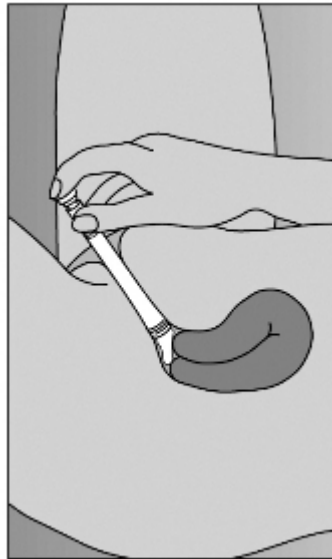


Figure C

Step 6. To clean: Pull plunger to remove it from barrel. Wash with mild soap and warm water (Figure D).

DO NOT BOIL OR USE HOT WATER.

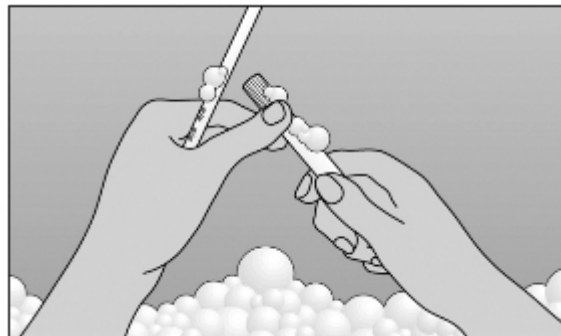


Figure D

Your doctor will tell you how long your treatment with PREMARIN cream will last. Do not stop treatment early. If you have the impression that the effect of PREMARIN cream is too strong or too weak, tell your doctor or pharmacist.

If you use more PREMARIN cream than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use PREMARIN cream

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

PREMARIN cream can have side effects.

Not all side effects reported for PREMARIN cream are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using PREMARIN cream, please consult your health care provider for advice.

If any of the following happens, stop using PREMARIN cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction including swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- stroke (symptoms of which may be facial drooping, weakness on side of the body, speech difficulties)
- heart attack (symptoms of which may be tightness or pain in the chest, neck, back or arms, tiredness, sweating)

Tell your doctor if you notice any of the following:

- vaginal inflammation, burning, irritation and itching
- persistent urge to urinate/burning sensation when urinating/passing frequent small amounts of urine
- vaginal yeast infections
- breast cancer
- cancer of the ovary

- painful lumps in the breasts
- cancer of the lining of the uterus (womb)
- enlargement of a non-cancerous tumour in the liver
- increased risk of growth of a tumour of the membranes around the brain or spinal cord
- red itchy bumps on the skin
- puberty occurring at an unusually early age
- high blood sugar
- low calcium levels in the blood
- changes in sex drive
- mood changes
- depression
- irritability
- memory loss (dementia)
- dizziness
- headache
- migraine
- nervousness
- worsening of chorea (a disorder characterised by jerky involuntary movements)
- discomfort wearing contact lenses
- blockage of the small veins in the eye causing blurred or loss of vision
- blood clot in the lungs
- blood clot in the deep veins of the leg, groin or arm
- nausea
- bloating
- stomach pain
- vomiting
- inflammation of the pancreas
- inflammation of the large intestine
- gallbladder disease

- jaundice (yellowing of the skin and eyes)
- hair loss
- dark, discoloured patches on the skin, often on the face
- male-pattern hair growth in women
- skin rash
- tender, red bumps, particularly on the shins
- joint pain
- leg cramps
- irregular vaginal bleeding or spotting
- painful menstruation/ pelvic pain
- breast pain
- breast tenderness
- breast enlargement
- discharge from the breast
- reactions from inserting PREMARIN cream such as vaginal burning, irritation and itching
- vaginal discharge
- enlargement of benign tumours of the uterus (fibroids)
- fluid retention
- changes in weight (increase or decrease)
- increased triglycerides (fatty substances in the blood)
- increase in blood pressure
- suicidal thoughts/behaviour and suicide

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA's

publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PREMARIN cream.

5. How to store PREMARIN cream

- Store all medicines out of reach of children.
- Store in a cool, dry place at or below 25 °C.
- For external use only.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PREMARIN cream contains

- The active substance is conjugated oestrogens. Each gram of PREMARIN cream contains 0,625 mg conjugated oestrogens in a non-liquefying base.
- The other ingredients are cetyl alcohol, cetyl esters wax, glycerin, glyceryl monostearate, methyl stearate, mineral oil heavy, propylene glycol monostearate, sodium lauryl sulphate, white wax and benzyl alcohol as the preservative

What PREMARIN cream looks like and contents of the pack

PREMARIN is a white cream containing 0,625 mg conjugated estrogens per gram, in a non-liquefying base.

Each pack contains a 42,5 g tube with one calibrated applicator.

Holder of Certificate of Registration

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