PREMARIN® TABLET

Conjugated estrogens (0.3 mg, 0.625 mg)

What is in this leaflet

What PREMARIN is used for

PREMARIN helps to relieve symptoms associated with deficiency of female hormone estrogen or female hypoestrogenism.
Symptoms such as:
-hot flushes and night sweats
-vaginal burning, itching, irritation, and dryness
-discomfort/pain during intercourse
-painful urination and an increased incidence of urinary tract infections
-urinary incontinence

After the menopause some women may be at risk of developing fragile bones (osteoporosis). PREMARIN helps to prevent and manage thinning of the bones which can cause fractures.

How PREMARIN works

PREMARIN is a Hormone Replacement Therapy (HRT). It contains the female hormone estrogen. It is like the hormones produced by the ovaries before menopause. When given during or after menopause, they can help control the symptoms.

Before you use PREMARIN

- *When you must not use it*

Do not take PREMARIN:
- if you have or have had breast cancer, or if you are suspected of having it;
- if you have cancer which is sensitive to estrogens, such as cancer of the lining of the womb (endometrium) or if you are suspected of having it;
- if you have excessive thickening of the womb lining (endometrial hyperplasia);
- if you are pregnant or think you are pregnant;
- if you have uterine bleeding of unknown cause;
- if you have or have had a blood clot in a vein, such as in the legs or the lungs;
- if you have or recently have had a disease caused by blood clots in the arteries, such as heart attack or stroke;
- if you are allergic to estrogen or any of the ingredients of PREMARIN;
- if you have liver disease;
- if you have a disorder affecting your blood clotting (such as protein C, protein S or antithrombin deficiency);

Pregnancy and lactation

Do not take PREMARIN if you are pregnant, trying to get pregnant or think you may be pregnant. If you find out you are pregnant while taking PREMARIN, you should stop taking it immediately and contact your doctor.
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Do not take 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 taking any medicine.

- *Before you start to use it*

Tell your doctor if you have:
- an increased risk of developing blood clots;
- migraine or severe headaches;
- if you're going to have surgery
- you are unable to walk for a long time because of major surgery, injury or illness
- endometriosis (material similar to the lining of the uterus growing outside the uterus, causing pain or bleeding)
- low blood calcium levels
- hereditary angioedema (swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing);
- heart or kidney problems;
- a very high level of fat in your blood (triglycerides);
  liver problems (e.g. a benign liver tumour), yellowing of the whites of the eyes or skin (jaundice) during pregnancy or when taking estrogen (e.g. birth control pill or HRT);
- asthma;
- epilepsy (fits);
- bone cancer
- a disease affecting the eardrum and hearing (otosclerosis);
- a condition called porphyria (a rare blood pigment disorder);
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE);
- underactive thyroid gland.

PREMARIN therapy can increase the risk of following:
- stroke;
- heart attack;
- memory loss
- blood clots in veins e.g. disturbed vision;
- blood clots in lungs;
- ovarian cancer;
- endometrial cancer;
- breast cancer
- gall bladder disease.

PREMARIN is not for use in children and females older than 65 years.

- *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:
- medicines used to treat certain types of depression (such as St. John's wort);
- medicines used for treatment of epilepsy (such as phenobarbital, phenytoin, carbamazepine, lamotrigine);

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- antibiotics (such as rifampicin, erythromycin and clarithromycin);
- antifungal medicines (such as ketoconazole and itraconazole);
- medicines used to reduce inflammation (dexamethasone);
- medicines used for treatment of HIV infections (such as ritonavir);
- medicines used to treat ulcers (such as cimetidine).

Grapefruit juice may increase concentrations of estrogens in the blood, and may result in side effects.

If you are scheduled for any laboratory tests, tell your doctor you are taking PREMARIN. Some blood tests may be affected by taking PREMARIN.

How to use PREMARIN

- *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.

For symptoms, associated with estrogen deficiency:
0.3 mg – 1.25 mg daily.

Osteoporosis: Initial dose:
0.3 mg.

Your doctor will start you on PREMARIN 0.3 mg daily. Your dose may be subsequently adjusted based on your clinical and bone mineral density responses.

PREMARIN therapy may be used continuously, with no interruption in therapy, or in cyclical regimens (regimens such as 25 days on the medicine followed by five days off the medicine).

Your doctor should review the need for treatment regularly.

- *When to use it*

Use as directed by your doctor or pharmacist.

PREMARIN tablets should be taken whole. Do not divide, crush, chew or dissolve tablets in mouth.

- *How long to use it*

Continue taking PREMARIN 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.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *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 taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness, tiredness and withdrawal bleeding in some females.

While you are using it

- *Things you must do*

Tell all the doctors, dentists and pharmacists treating you that you are taking PREMARIN.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

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

Do not take any new medicines without consulting your doctor.

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

- *Things to be careful of*

Driving and using machines

There are no studies performed on the effect of PREMARIN on the ability to drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effects:
- hair loss,
- joint pain, leg cramps;
- abnormal uterine bleeding, such as breakthrough bleeding or spotting, changes in menstrual flow, breast pain, breast tenderness, breast enlargement, swollen breasts, discharge from the nipples, vaginal discharge;
- changes in weight (increased or
- decreased) and high level of fat
- (triglyceride) in blood.

Other side effects:
- heart attack;
- severe high blood calcium level;
- increased blood pressure;
- fluid retention.

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

Storage and Disposal of PREMARIN

- *Storage*

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Keep out of the reach and sight of children.

Do not store above 30°C.

- *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*

Premarin tablet 0.3 mg
Green, oval, biconvex, coated tablet branded 0.3 in white ink.
Premarin tablet 0.625 mg
Maroon, oval, biconvex, coated tablet branded 0.625 in white ink
Tablets are supplied in blister packs of 28.

Some product strengths or pack sizes may not be available in your country

- *Ingredients*
  - Active ingredient:

Conjugated estrogens

  - Inactive ingredients:

Tablet cores: Lactose Monohydrate (Spray Dried), Hypromellose 2208, K100M, Microcrystalline Cellulose, Magnesium stearate, Purified water.

Tablet coating: Sucrose, Microcrystalline Cellulose, Hydroxypropyl Cellulose, Hypromellose, 2910, E6, Hypromellose 2910, E15, Polyethylene Glycol 400, Purified water, Carnauba Wax, Opacode WB NS-78-18011, White Ink,

Opadry Green 15B21511 for Premarin Tablet 0.3 mg,
Opadry Maroon 03B16083 for Premarin Tablet 0.625 mg.

- *MAL number*

Product Name	Registration Number
Premarin 0.3 mg tablet	MAL19991386ASZ
Premarin 0.625 mg tablet	MAL19870652AZ

Manufacturer
Manufactured by:
Pfizer Ireland Pharmaceuticals Unlimited Company,
Little Connell, Newbridge,
W12 HX57,
Ireland

Product Registration Holder
Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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