PREMARIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using PREMARIN?

PREMARIN contains the active ingredient conjugated estrogens. PREMARIN is used to relieve symptoms or discomfort during or after menopause. It is also used to prevent thinning of the bones (osteoporosis) and to treat women where the ovary does not function properly or has been removed.

For more information, see Section 1. Why am I using PREMARIN? in the full CMI.

2. What should I know before I take PREMARIN?

Do not take if you have ever had an allergic reaction to conjugated estrogens, any other similar medicines such as Menopausal Hormonal Therapy medicines or oral contraceptives ("birth control pills"), or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take PREMARIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PREMARIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take PREMARIN?

- For prevention of osteoporosis, take one tablet daily. For symptoms of menopause, take one or two tablets daily. For women without fully functioning ovaries, take as directed by your doctor.
- Swallow the tablets whole with a full glass of water. Do not divide, crush, chew, or dissolve the tablet in your mouth.

More instructions can be found in Section 4. How do I take PREMARIN? in the full CMI.

5. What should I know while using PREMARIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using PREMARIN. • See your doctor regularly for checkups and to review whether changes to your dose may be required. • Check your breasts regularly. • Tell your doctor if you become pregnant. Use non-hormonal birth control while taking PREMARIN.
Things you should not do	• Do not change your dose without telling your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PREMARIN affects you. PREMARIN may cause dizziness in some people.
Drinking alcohol	• No information available.
Looking after your medicine	• Keep your tablets where the temperature stays below 25°C. • Keep your tablets in the blister pack until it is time to take them.

For more information, see Section 5. What should I know while using PREMARIN? in the full CMI.

6. Are there any side effects?

Side effects include: abnormal bleeding or spotting in your underwear; period-like pain or pelvic pain; changes to your vaginal discharge; sore, swollen or irritated breasts; lumps in your breast; weight changes; acne or rash; changes to your mood. Serious side effects include: signs of a stroke, heart attack or blood clot, sudden partial or complete vision loss.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING:

Endometrial cancer

- **Let your doctor know if you experience persistent or recurring abnormal vaginal bleeding with use of PREMARIN that has not been previously diagnosed. Your doctor will conduct necessary investigations to rule out endometrial cancer.**

Heart or blood vessel disease and other risks

- **PREMARIN should not be used for prevention of heart disease or dementia.**
- **The use of PREMARIN may increase your risk of stroke, blood clots or dementia over time.**
- **The use of PREMARIN in combination with a progestogen may increase your risk of heart attack, stroke, breast cancer, blood clots or dementia over time.**

PREMARIN should be used at the lowest effective dose and the shortest duration of time according to your treatment goals and risks. Your doctor will assess and discuss the risks and benefits of taking this medicine with you.

PREMARIN®

Active ingredient: *conjugated estrogens*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREMARIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREMARIN.**

Where to find information in this leaflet:

1. Why am I taking PREMARIN?
2. What should I know before I take PREMARIN?
3. What if I am taking other medicines?
4. How do I take PREMARIN?
5. What should I know while taking PREMARIN?
6. Are there any side effects?
7. Product details

1. Why am I taking PREMARIN?

PREMARIN contains the active ingredient conjugated estrogens. PREMARIN is a type of treatment called menopausal hormone therapy (MHT) (previously known as hormone replacement therapy, HRT) and contains the hormone estrogen in the form known as conjugated estrogens.

PREMARIN is used to relieve the discomfort many women feel during and after menopause, including symptoms such as "hot flushes", sweating and vaginal dryness. It helps to prevent thinning of the bones (osteoporosis), which can cause fractures.

PREMARIN is also used to treat women where either the ovary does not function properly or has been removed.

How it works

Menopause occurs naturally in women, typically between the ages of 45 and 55. During menopause, your body produces less estrogen than it did beforehand. This can cause symptoms such as "hot flushes". Some women also have problems with dryness of the vagina causing discomfort during or after sexual intercourse. Some women develop osteoporosis during or after menopause. This is a thinning of the bones making them weaker and more likely to break, especially the bones of the spine, hip and wrist.

Conjugated estrogens are like the hormones produced by the ovaries before menopause. When given during or after menopause, they can help control the symptoms.

Estrogen is used treat women who have had their uterus (womb) removed. If you have not had your uterus removed, you will need to take an estrogen with a progestogen.

2. What should I know before I take PREMARIN?

Warnings

Do not take PREMARIN if:

- you are allergic to conjugated estrogens, any other similar medicines such as other MHT medicines or oral contraceptives ("birth control pill"), or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can take this medicine.
- you have or have had any of the following medical conditions:
  - breast cancer or problems with your breasts that your doctor has not investigated or is in the process of investigating
  - endometrial, ovarian or cervical cancer
  - abnormal genital bleeding, which your doctor has not investigated or is in the process of investigating.
  - a problem with blood clots forming in your blood vessels, such as painful inflammation of the veins (thrombophlebitis) or the blockage of a blood

vessel in the legs (deep vein thrombosis or DVT), or lungs (pulmonary embolism)
    - heart disease or stroke
    - very high blood pressure that is not properly controlled
    - liver disease
    - blood clotting problems
- you are pregnant, or suspect you are pregnant

Check with your doctor if you:

- are allergic to any foods, dyes, preservatives or any other medicines
- have any other medical conditions, including:
    - nodules, lumps or cysts in your breasts or any other benign breast condition (not cancer)
    - fibroids or other benign tumours of the uterus (not cancer)
    - unusual or irregular genital bleeding or spotting
    - endometriosis (material similar to the lining of the uterus growing outside the uterus, causing pain or bleeding)
    - high blood pressure
    - liver problems
    - a condition called porphyria
    - hearing difficulties
    - yellowing of the whites of the eyes or skin (jaundice) during pregnancy or when taking estrogen (e.g. birth control pill or MHT)
    - fluid retention or angioedema
    - kidney problems
    - heart problems
    - diabetes
    - migraine
    - asthma
    - epilepsy
    - Lupus (systemic lupus erythematosus)
    - hereditary angioedema (swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing)
    - dementia
    - gall bladder disease
    - a high level of blood fats (triglycerides)
    - high or low levels of calcium in the blood
    - underactive thyroid gland
    - obesity
- take any medicines for any other condition
- have had breast cancer, or if anyone in your immediate family has
- have had blood clots in the deep veins of the legs or blood vessels of lungs, a stroke or heart attack, or if anyone in your immediate family has
- are under 18 years of age. PREMARIN should not be used in children.
- If you smoke

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or think you are pregnant.

You must confirm that you are not pregnant before you take PREMARIN.

Tell your doctor if you are pregnant, intend to become pregnant or become pregnant while taking PREMARIN.

PREMARIN is not a contraceptive. Since pregnancy may be possible early in the menopause, while you are still having menstrual periods, you should ask your doctor about using a non-hormonal method of birth control.

Do not take PREMARIN if you are breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Estrogens have been found in breast milk and may also reduce the production of breast milk.

PREMARIN will not help to restore fertility.

Starting PREMARIN

- You must have a thorough medical check-up before starting PREMARIN for the first time or if you are taking it again after a break.
- MHT should only be used if you have been fully informed of the risks.
- The decision to use MHT should be based on your particular needs and health and made after a careful medical evaluation.

3. What if I am taking other medicines?

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

Some medicines may interfere with PREMARIN and affect how it works.

Medicines that may <u>reduce</u> the effect of PREMARIN include:

- herbal medicines containing St John's Wort
- medicines for epilepsy such as phenytoin, phenobarbitone and carbamazepine
- antibiotics such as rifampicin
- corticosteroids such as dexamethasone

Medicines that may cause <u>increase side effects</u> when taken with PREMARIN include:

- cimetidine
- antibiotics such as erythromycin and clarithromycin
- anti-fungal agents such as ketoconazole and itraconazole
- thyroid replacement therapy
- ritonavir, a medicine used for the treatment of HIV infection
- cyclosporin, a medicine used to prevent organ rejection.

PREMARIN may reduce the effect of other medicines including:

- lamotrigine, a medicine used for epilepsy
- medicines used to treat high blood pressure
- some medicines used for depression, anxiety or other psychiatric conditions, such as tricyclic antidepressants, diazepam and phenothiazines.
- corticosteroids
- theophylline, used for asthma and other lung conditions

Grapefruit juice may also affect how well PREMARIN works and PREMARIN may have an effect on caffeine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PREMARIN.

4. How do I take PREMARIN?

How much to take

- For prevention of osteoporosis, take one tablet daily.
- For symptoms of menopause, take one or two tablets daily, as instructed by your doctor.
- For women without fully-functioning ovaries, your doctor will prescribe PREMARIN according to your needs. The dose may be higher or lower than that prescribed for the treatment of menopause symptoms.
- For women with a uterus, your doctor will also prescribe a progestogen tablet to be taken with your PREMARIN. For some women with a history of endometriosis, who have had a hysterectomy, a progestogen may also be needed. Your doctor will advise you.

When to take PREMARIN

- PREMARIN should be taken at the same time each day, or as advised by your doctor.
- It does not matter if you take PREMARIN before or after food.

Taking PREMARIN for the first time

- If you are not already using any type of MHT you can start PREMARIN on any convenient day. If you do not have predictable periods, then start PREMARIN on a Monday as this matches the directions on the calendar pack.
- If you are already using a different type of MHT, your doctor can advise you when to start PREMARIN.

How to take PREMARIN

- Swallow tablets whole with a full glass of water. Do not divide, crushed, chew, or dissolve the tablet in your mouth.
- Take all tablets in a blister pack before starting a new pack.
- Follow the instructions provided and use PREMARIN until your doctor tells you to stop.

If you forget to take PREMARIN

PREMARIN should be taken regularly at the same time each day, or as advised by your doctor.

If you miss your dose at the usual time and more than 12 hours has passed, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If less than 12 hours has passed from the time you normally take PREMARIN, take the missed tablet and then take the next tablet at the usual time.

If you take too much PREMARIN

If you think that you have taken too much PREMARIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include:

- feeling sick or vomiting
- dizziness
- feeling sleepy or tired
- breast tenderness
- stomach pain
- women may also experience vaginal bleeding

5. What should I know while taking PREMARIN?

Things you should do

- Talk regularly with your doctor about whether you still need treatment with PREMARIN.
  Treatment with estrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.
- Check your breasts regularly. Your doctor or nurse can show you how to check your breasts properly. If you notice any changes to your breasts, see your doctor.
- Include foods that are good sources of calcium and vitamin D in your daily diet, and exercise regularly. Calcium, vitamin D and exercise may help prevent thinning of the bones. Your doctor can advise you on which foods and types of exercise are best for you.

Tell your doctor if you:

- need to have blood tests. PREMARIN can affect the results of some tests, including hormone and liver function tests.
- are planning for any hospitalisation or surgery. Tell your doctor well in advance (at least 4 to 6 weeks).

- go to hospital unexpectedly. Tell the doctor who admits you that you are taking PREMARIN.
  The risk of developing blood clots in your blood vessels may be temporarily increased as a result of an operation, serious injury or having to stay in bed for a prolonged period.
- have any breakthrough bleeding or spotting, which persists after 2 to 3 months of treatment with PREMARIN.
  Breakthrough bleeding or spotting may occur during the first few months of treatment and then stop. However, if the bleeding continues, your doctor may wish to check why it is happening.
- experience symptoms such as pressure, discomfort or pain in your stomach or pelvis; swollen or bloated stomach; appetite loss; changes in toilet habits (e.g., constipation, diarrhoea, weeing (passing urine) more frequently, increased flatulence); heartburn and nausea; tiredness; unexplained weight loss or weight gain, especially if these symptoms are new for you or continue for a few weeks.
  Having these symptoms does not necessarily mean you have ovarian cancer, but it is best to have a check-up. Your doctor will physically check your pelvic organs and conduct blood tests, to rule out ovarian cancer.
- experience any abnormal problems with your vision

Call your doctor straight away if you:

- Become pregnant while taking PREMARIN. PREMARIN should not be taken while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using PREMARIN.

Things you should not do

- PREMARIN should not be taken, either alone or with a progestogen, to prevent heart attacks, stroke or dementia. Your doctor will advise you.
- Do not take PREMARIN to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else even if they have the same condition as you.
- Do not stop taking PREMARIN or change the dosage without checking with your doctor.

See your doctor regularly

See your doctor at least every six months for a checkup. Some women may need to go more often.

Your doctor will at regular intervals:

- check your breasts
- send you to have a mammogram
- check your uterus and cervix
- do a Pap smear
- check your blood pressure.

Your doctor may also take blood to check your blood fats, sugar levels and liver function.

This helps to monitor for any unwanted effects of MHT.

If you have used PREMARIN as MHT for 5 or more years, there may be a slight increase in risk of you developing ovarian cancer.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PREMARIN affects you.

PREMARIN may cause dizziness in some people

Drinking alcohol

No information available.

Looking after your medicine

- Keep your tablets where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take them out of the blister, they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Changes to your vaginal discharge: • abnormal bleeding or spotting in your underwear (if bleeding is heavy check with your doctor as soon as possible) • vaginal discharge or change in secretions • vaginal thrush **Changes to your breasts:** • tender, painful or swollen breasts, or secretions from the breasts • lumps in your breasts or armpits	**Speak to your doctor if you have any of these side effects and they worry you.**

Side effects	What to do
• irritation or dimpling of breast skin • redness or flaky skin in the nipple area or the breast **Pain or discomfort in your stomach area:** • period-like pain or pelvic pain • stomach swelling or passing wind **Feeling unwell:** • nausea or vomiting • fever • fast heartbeat • headache or migraine • dizziness **Changes to your body or bodily functions:** • loss of hearing • loss of memory • irregular, rapid jerky movements • swelling of the lower legs, ankles or fingers • swelling and redness along a vein which is extremely tender to touch • weight changes • acne, itchy skin, or skin discolouration • skin rash • hair loss or extra hair growth • intolerance to contact lenses • worsening of porphyria **Changes to your mood:** • depression or anxiety • problems sleeping or sleepiness • moodiness or irritability • changes in sex drive	
Symptoms of an allergic reaction: • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin. **Signs of a stroke or heart attack:** • sudden severe headache • sudden loss of coordination, blurred vision, slurred speech • numbness or tingling in an arm or leg • confusion or difficulty understanding • vision problems **Signs of a blood clot:**	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• painful swelling in the calves or thighs • chest pain • difficulty breathing • coughing blood **Changes to your vision:** • sudden partial or complete loss of vision or other problems with your eyesight **Pain or feeling unwell:** • pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting • bloody and watery poo (diarrhoea), abdominal pain or tenderness, fever, nausea or vomiting. **Changes to your skin or poo:** • a yellow colour to the skin or eyes, itching, dark coloured wee (urine) or light coloured poo (bowel motion).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Ovarian Cancer

Clinical trials have reported a slight increase in risk of ovarian cancer in women aged between 50-54 years old when PREMARIN alone or in combination with a progestogen is taken for over 5 years.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PREMARIN contains

Active ingredient (main ingredient)	conjugated estrogens • Each PREMARIN 0.3 mg tablet contains 0.3 mg of conjugated estrogens.

	• Each PREMARIN 0.625 mg tablet contains 0.625 mg of conjugated estrogens
Other ingredients **(inactive ingredients)**	• lactose monohydrate • hypromellose • microcrystalline cellulose • powdered cellulose • calcium phosphate • sucrose • hyprolose • magnesium stearate • macrogol 400 • carnauba wax • Opacode white ink PREMARIN 0.3 mg tablets also contain Opadry green. PREMARIN 0.625 mg tablets also contain Opadry maroon.
Potential allergens	• lactose monohydrate • sucrose PREMARIN 0.625 mg tablets only: • azo dye FD&C Red #40 (E129)

Do not take this medicine if you are allergic to any of these ingredients.

PREMARIN does not contain gluten or tartrazine.

What PREMARIN looks like

PREMARIN 0.3 mg tablets are dark green and are marked "0.3", provided in blister packs.

AUST R 177673

PREMARIN 0.625 mg tablets are maroon (dark red) and are marked "0.625", provided in blister packs.

AUST R 177674

Who distributes PREMARIN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

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