

# Premarin<sup>®</sup>

Conjugated oestrogens Tablets

## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some of the common questions about Premarin Tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking Premarin against the benefits this medicine is expected to have for you.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Premarin is used for

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Premarin is a type of treatment called hormone replacement therapy (HRT) and contains the hormone oestrogen in the form known as conjugated oestrogens.

Premarin helps 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.

If your doctor thinks you will need to take oestrogens for a long time, including for the prevention of

osteoporosis, he or she will have considered the benefits and risks of other treatments before prescribing Premarin for you.

### How it works

Menopause occurs naturally in women, typically between the ages of 45 and 55. During menopause, your body produces less oestrogen 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 oestrogens are like the hormones produced by the ovaries before menopause. When given during or after menopause, they can help control the symptoms.

Oestrogen is used to treat women who have had their uterus or "womb" removed. If you have not had your uterus or "womb" removed, you will need to take an oestrogen with a progestogen.

**Ask your doctor if you have any questions why Premarin has been prescribed for you.**

Your doctor may have prescribed Premarin for another use.

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

Premarin is not habit-forming.

Premarin is not suitable for birth control and it will not restore fertility.

This medicine is not expected to affect your ability to drive a car or operate machinery.

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### Before you take Premarin

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#### **When you must not take Premarin**

**HRT should only be used if you have been fully informed of the risks.**

The decision to use HRT should be based on your particular needs and health, and made after a careful medical evaluation.

**Do not take Premarin, with or without a progestogen to prevent heart attacks, stroke or dementia.**

A study called the Women's Health Initiative reported an increased risk of stroke and blood clots in the legs in women taking conjugated oestrogens 0.625 mg. The study also reported an increased risk of heart attack, stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated oestrogens 0.625 mg and the progestogen, medroxyprogesterone acetate (MPA).

The Women's Health Initiative Memory Study reported an increased risk of dementia in women aged 65 years and over taking conjugated oestrogens and MPA.

It is assumed that these risks will be similar for other medicines containing oestrogen and progestogen combinations.

**Talk regularly with your doctor about whether you still need treatment with Premarin.**

Treatment with oestrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

**Do not take Premarin if you have an allergy, or think you have an allergy, to:**

- Any medicine containing conjugated oestrogens, the active ingredient in Premarin
- Any of the ingredients listed at the end of this leaflet
- Any other similar medicines, such as other HRT medicines or oral contraceptives ("birth control pill").

Some of the symptoms of an allergic reaction may include:

- 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.

**Do not take Premarin if you have or have had any of the following medical conditions:**

- Breast cancer
- Endometrial or cervical cancer
- Abnormal genital bleeding, which your doctor has not investigated.
- 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
- Problems with your breasts that your doctor has not investigated
- Liver disease
- Blood clotting problems.

**If you are not certain whether these may apply to you, or you are**

**worried about anything in this list tell your doctor.**

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

Pregnancy must be excluded before you take Premarin.

**Do not give this medicine to a child.**

**Do not take Premarin if you are breast feeding.**

Oestrogens have been found in breast milk, and may reduce the production of breast milk.

**Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.**

If it is expired or damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

***Before you start to take 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.**

**Tell your doctor if you are allergic to any foods, dyes preservatives or any other medicines.**

**Tell your doctor if you have:**

- A family history of breast cancer
- 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 oestrogen (e.g. birth control pill or HRT)
- Fluid retention
- 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)
- Gall bladder disease
- A high level of blood fats
- High or low levels of calcium in the blood
- Underactive thyroid gland
- Obesity.

**Tell your doctor if anyone in your immediate family has had blood clots in the deep veins of the legs or blood vessels of lungs, a stroke or heart attack.**

***Taking Other Medicines***

**Tell your doctor if you are taking birth control pills.**

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 another (non-hormonal) method of birth control.

**Tell your doctor or pharmacist if you are taking any other medicines including:**

- All prescription medicines
- All medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Premarin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are taking any of the following:**

- Herbal medicines containing St John's Wort
- Some medicines for epilepsy such as phenytoin, phenobarbitone and carbamazepine
- Some antibiotics and anti-infectives such as rifampicin, erythromycin and clarithromycin
- Anti-fungal agents such as ketoconazole and itraconazole
- Thyroid replacement therapy
- Corticosteroids, such as dexamethasone
- Ritonavir for the treatment of HIV infection
- Cyclosporin used to prevent organ rejection.

Grapefruit juice may also affect how well Premarin works.

**If you have not told your doctor about any of the above, tell them before you start taking Premarin.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

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## How to take Premarin

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### **How to take it**

**Swallow tablets whole with a full glass of water.**

### **When to take Premarin**

If you are not already using any type of HRT you can start Premarin on any convenient day. However, it is recommended you start Premarin after your last period. 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 HRT, your doctor can advise you when to start Premarin.

It does not matter if you take Premarin before or after food.

### **How much to take**

For symptoms of menopause and prevention of osteoporosis, take one tablet daily.

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.

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.

Take all tablets in a blister pack before starting a new pack.

### **How long to take it**

**Continue to take your medicine for as long as your doctor tells you.**

Your doctor can discuss the risks and benefits of long-term treatment with HRT in your particular case.

### **If you forget to take your tablets**

**If less than 12 hours has passed from the time you normally take Premarin, take the missed tablet.**

Take the next tablet at the usual time.

**If more than 12 hours has passed, discard the missed tablet and take the next tablet when you normally would.**

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### **If you take too much (Overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 0800 POISON or 0800 764 766) or go to Accident and Emergency at the nearest hospital if you think you or anybody else has taken too much Premarin.**

**Do this even if there are no signs of discomfort or poisoning.**

**You may need urgent medical attention.**

Symptoms of an overdose may include:

- Feeling sick or vomiting
- Dizziness
- Feeling sleepy or tired
- Breast tenderness
- Stomach pain
- Women may also experience menstrual bleeding.

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## While you are taking Premarin

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### **Things you must do**

**Tell any doctors, dentists and pharmacists who are treating you that you are taking Premarin.**

**If you are about to take any new medicines, tell your doctor or pharmacist that you are taking Premarin.**

**If you become pregnant while using Premarin, see your doctor immediately.**

Premarin should not be used while you are pregnant.

**See your doctor at least every six months for a check up.**

Some women may need to go more often.

Your doctor will:

- Check your breasts and order a mammogram at regular intervals
- Check your uterus and cervix and do a Pap smear at regular intervals
- 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 HRT.

**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 well in advance (at least 4 to 6 weeks) of any expected hospitalisation or surgery.**

**If you 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.

**Tell your doctor if you 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.

### ***Things you must not do***

**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.**

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## **Side Effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Premarin.**

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

It can be difficult to tell whether side effects are the result of taking Premarin or are side effects of another medicine you are taking.

**Do not be alarmed by the list of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- Signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body;

shortness of breath, wheezing or troubled breathing.

- Signs that clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood.
- Sudden partial or complete loss of vision or other problems with your eyesight.
- Pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting.
- A yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions.
- Bloody diarrhoea, abdominal pain or tenderness, fever, nausea or vomiting.

Whilst these side effects are rare, they are serious. You may need, urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following and they worry you:**

- Abnormal genital bleeding or spotting (if bleeding is heavy check with your doctor as soon as possible)
- Tender, painful or swollen breasts, or secretions from the breasts
- Period-like pain or pelvic pain
- Vaginal discharge or change in secretions
- Vaginal thrush
- Stomach pain
- Stomach swelling or passing wind
- Nausea or vomiting
- Headache or migraine
- Loss of hearing
- Loss of memory
- Irregular, rapid jerky movements
- Dizziness

- Depression or anxiety
- Problems sleeping or sleepiness
- Moodiness or irritability
- Changes in sex drive
- 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.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

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## After taking Premarin

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### Storage

**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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

**Do not store Premarin, or any medicine, in a bathroom or near a sink. Do not leave Premarin in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking Premarin, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product Description

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### What it looks like

Premarin tablets are available in two different strengths:

- Premarin 0.3mg tablets
- Premarin 0.625mg tablets

Each strength comes in a pack of 28 tablets.

### Ingredients

The active ingredient is conjugated oestrogens.

Each dark green Premarin 0.3mg tablet contains conjugated oestrogens 0.3mg and is marked "0.3".

Each maroon Premarin 0.625mg tablet contains conjugated oestrogens 0.625 mg and is marked "0.625".

The following inactive ingredients are also found in all strengths of Premarin:

- Lactose
- Methylcellulose
- Microcrystalline cellulose
- Sucrose
- Magnesium stearate
- Calcium phosphate
- Calcium sulfate
- Glyceryl mono-oleate
- Macrogol 20000
- Shellac
- Stearic acid
- Titanium dioxide
- Carnauba wax
- Ink White, Opacode S-8-28905

The colouring agent found in Premarin 0.3 tablet is Opalux Green.

Opalux Green contains the following ingredients:

- Sucrose
- Sodium benzoate
- Iron Oxide Yellow (CI77492)
- Indigo Carmine (CI73015)
- Titanium Dioxide
- Povidone
- Methyl hydroxybenzoate
- Propyl hydroxybenzoate.

The colouring agent found in Premarin 0.625mg tablets is Opalux Maroon.

Opalux Maroon contains the following ingredients:

- Sucrose
- Sodium benzoate
- Erythrosine (CI45430)
- Sunset yellow FCF (CI15985)
- Titanium dioxide
- Indigo Carmine (CI73015)
- Povidone.

### Manufacturer

Premarin Tablets are supplied in Australia by

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

Premarin Tablets are supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland, New Zealand

Toll Free number: 0800736363

Australian Registration Numbers:

Premarin 0.3 tablets

AUST R 51693

Premarin 0.625 tablets

AUST R 51708

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