

Premarin®

Conjugated oestrogens Tablets

Consumer Medicine Information

What is in this leaflet

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 they expect it will provide.

If you have any concerns about using Premarin, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with the medicine

You may need to read it again.

When you must not use Premarin

Do not use Premarin or other oestrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated an increased risk of stroke and blood clots in the legs in women receiving conjugated oestrogens 0.635 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 researchers stopped the study after 5 years when

it was determined the risks were greater than the benefits in this group. The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65-79 years taking conjugated oestrogens and MPA. There are no comparable data currently available for other doses of conjugated oestrogens and MPA or other combinations of oestrogens and progestogens. Therefore, you should assume the 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.

What Premarin is used for

Premarin is a type of treatment called hormone therapy (HT) and contains the hormones called conjugated oestrogens.

Premarin helps to relieve the discomfort many women feel during and after the menopause. It also helps to prevent thinning of the bones (osteoporosis), which can cause fractures.

Premarin is also used in the treatment of female hypogonadism, 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, your doctor will have considered the benefits and risks of other treatments before prescribing Premarin for you.

How it works

Conjugated oestrogens are a mixture of natural female sex hormones. They are like the hormones that your ovaries were producing before menopause.

The menopause occurs naturally in women usually between the ages of 45 and 55. During menopause, your body produces less oestrogen than it did before. This can cause unpleasant symptoms such as a feeling of warmth in the face, neck and chest, "hot flushes", which are like sudden, intense feelings of heat and sweating throughout the body. Some women also have problems with dryness of the vagina causing discomfort during or after sexual intercourse.

Oestrogens can be given to reduce or eliminate these symptoms.

After the age of 40, and especially after the menopause, some women develop osteoporosis. This is a thinning of the bones that makes them weaker and more likely to break, especially the bones of the spine, hip and wrist. The risk of osteoporosis is increased by a lack of oestrogen. Oestrogens can be given to reduce this risk.

Women who still have a uterus must take both oestrogen and progestogen as part of HT. This is because oestrogen stimulates the growth of the lining of the uterus (called the endometrium). Before menopause this lining is shed during your period through the action of a natural progestogen.

After menopause, taking oestrogen on its own as HT may lead to irregular bleeding and a disorder of the uterus lining called endometrial hyperplasia, which can become endometrial cancer. Progestogens help protect the lining of the uterus from developing this disorder.

If you do not have a womb, you do not need to take a progestogen as part of HT.

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

Premarin has been approved for the uses listed above. However, your doctor may have prescribed it for another use.

Premarin is available only with a doctor's prescription. It is not habit-forming.

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

Before you take Premarin

When you must not take it

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

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

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

- Conjugated oestrogens, the active ingredient in Premarin
- Any of the ingredients listed at the end of this leaflet
- Any other medicine containing oestrogen, including the birth control pill.

Signs of allergy include a skin rash, itching, shortness of breath and/or a swollen face, lips, tongue or other parts of the body.

Do not take Premarin if you have:

- Cancer of the breast or uterus or any other oestrogen dependent cancer, or you have had this condition in the past or think you have one of these conditions.
- A problem with blood clots forming in your blood vessels, now or in the past. You may have had painful inflammation of the veins (thrombophlebitis) or blockage of a blood vessel in the legs (deep vein thrombosis), or lungs (pulmonary embolism).
- Heart disease or have recently had a stroke.
- Abnormal genital bleeding, which your doctor has not checked out.
- Problems with your breasts, which your doctor has not checked out.
- Liver disease.
- Severe uncontrolled high blood pressure.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Do not take Premarin if you are pregnant or think you are pregnant or you are breast-feeding.

It may harm your baby. Oestrogens have been found in breast milk and may reduce the production of breast milk.

Do not take Premarin after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If this is the case, take the tablets back to your pharmacist.

If you are not sure whether you should take Premarin, contact your doctor.

Before you start to take it

You must have a thorough medical check-up before starting Premarin for the first time or recommencing Premarin.

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 bleeding or spotting from the vagina
- Endometriosis
- High blood pressure
- Liver problems, including yellowing of the skin or whites of the eyes and a condition called porphyria
- Had a problem in the past with a condition called cholestatic jaundice when you were pregnant or took an oestrogen (eg birth control pill or HT)
- Kidney problems
- Heart problems
- Diabetes
- Migraine
- Asthma
- Epilepsy
- Systemic lupus erythematosus
- Hereditary angioedema
- Gall bladder disease
- A high level of triglycerides (fats) in the blood
- High or low levels of calcium in the blood.

Tell your doctor if you are likely to have an increased risk of developing blood clots in your blood vessels. The risk increases as you get older and it may also be increased if:

- Anyone in your immediate family has ever had blood clots in the blood vessels of the legs or lungs
- You are overweight
- You have a disorder called systemic lupus erythematosus (SLE).

If you have not told your doctor about any of these things, tell them before you start taking Premarin.

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 to suggest another (non-hormonal) method of birth control.

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

Some medicines and Premarin may interfere with each other. These include:

- 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
- Dexamethasone
- Ritonavir for the treatment of HIV infection
- Cyclosporin used to prevent organ rejection.

Premarin may affect these medicines or they may affect how well Premarin works. You may need to take different amounts of your medicines or take different medicines.

Grapefruit juice may also affect how Premarin works.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while you are using Premarin.

How to Take Premarin

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

These instructions 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.

When to start it

If you are not already using any type of HT 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 HT, your doctor can advise you when to start Premarin.

How much to take

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

For women with a womb, 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 symptoms of female hypogonadism, your doctor will prescribe Premarin according to your needs. The dose may be higher or lower than that prescribed for the treatment of menopausal symptoms.

Swallow the tablets whole with a glass of water.

Premarin can be taken with a meal or between meals.

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

How long to take it

Although some women have no symptoms of the menopause or only

mild ones, and may not need extra hormones, other women may need to use Premarin.

Your doctor can advise you how long you may need to take Premarin.

Your doctor can discuss the risks and benefits of long-term treatment with HT in your particular case. Studies on the use of oestrogens in postmenopausal women have reported inconsistent results on the risk of breast cancer. Some recent studies have shown that women using HT have a small increase in breast cancer risk after several years of use, while others have not. The risk increases with the length of HT use. Some studies have shown that oestrogens may be associated with a small increase in the risk of ovarian cancer after a number of years of use, while other studies have not.

A recent study has also shown that oestrogens are associated with a small increase in the risk of strokes and blood clots. On the other hand the risk of hip fractures may be reduced.

Another study has shown that in women older than 65 years, HT is associated with a small increase in the risk of dementia, including Alzheimer's disease. It is not known if this finding applies to younger women.

If you forget to take it

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.

Overdose

Telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think you or anybody else has taken too much Premarin.

If you have taken too much, symptoms you may get include nausea, vomiting, breast tenderness, dizziness, stomach pain, and drowsiness or tiredness. Women may also get withdrawal bleeding.

While you are taking Premarin

Things you must do

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

It should not be used while you are pregnant.

See your doctor at least every six months for a check up. Some women will 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 fat and sugar levels and liver function.

This helps to prevent unwanted effects of HT.

Conduct monthly self-examination of your breasts.

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 using 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 this is happening.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking Premarin.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Premarin.

Things you must not do

Do not use Premarin to treat any other complaints unless your doctor tells you to.

Do not give Premarin to anyone else, even if their symptoms seem to be the same as yours.

Side Effects

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

All medicines have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible 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.

The above side effects are serious, requiring urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice any of the following:

- Abnormal bleeding or spotting from the uterus (if bleeding is heavy check with your doctor as soon as possible)
- Tender, painful or swollen breasts, secretions from the breasts
- Period-like pain or pelvic pain
- Vaginal discharge or change in secretions

- Vaginal thrush
- Enlargement of fibroids in the uterus
- Stomach cramps or swelling or passing wind
- Nausea or vomiting
- Headache or migraine
- 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 due to fluid retention
- 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
- Enlargement of a pre-existing benign liver tumour or pre-existing benign brain tumour
- Inflammation of the pancreas.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After taking Premarin

Storage

Keep your Premarin Tablets below 25°C.

Keep Premarin tablets in the pack until it is time to take them.

Do not leave Premarin in the car or on windowsills.

Do not store Premarin, or any medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep Premarin where young 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

Once you have finished taking Premarin Tablets ask your pharmacist what to do with any that are left over.

Product Description

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 by

Wyeth Australia Pty Limited

ABN 16 000 296 211

17-19 Solent Circuit

Baulkham Hills NSW 2153

If you would like more information about Premarin, call Wyeth on free call 1800 500 498 or email medinfo@wyeth.com.

Australian Registration Numbers:

Premarin 0.3 tablets

AUST R 51693

Premarin 0.625 tablets

AUST R 51708

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