

Premia[®] 2.5 Continuous & Premia 5 Continuous

Conjugated Oestrogens and Medroxyprogesterone acetate Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Premia Continuous 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 Premia Continuous against the benefits they expect it will have for you.

If you have any concerns about this medicine, 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.

What Premia Continuous is used for

Premia Continuous is a type of treatment called hormone replacement therapy (HRT) and contains the hormones conjugated oestrogens and medroxyprogesterone acetate (MPA).

Premia Continuous helps to relieve the discomfort many women feel during and after menopause, including symptoms such as "hot flushes", sweating and vaginal dryness. It also helps to prevent

thinning of the bones (osteoporosis), which can cause fractures, in some women. Premia Continuous is used by women who still have a uterus (womb).

If your doctor thinks you will need to take HRT 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 Premia Continuous for you.

How it works

Menopause occurs naturally in women usually 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", 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. Some women develop osteoporosis during or after menopause. 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.

Conjugated oestrogens and medroxyprogesterone acetate are like the hormones produced by the ovaries before menopause.

When given during or after menopause, oestrogens can help control the symptoms.

Women who still have a uterus must take both oestrogen and progestogen

as part of HRT. This is because, after menopause, taking oestrogen on its own as HRT may lead to irregular bleeding and a disorder of the lining of the uterus (endometrium) called endometrial hyperplasia, which can become endometrial cancer.

Progestogens such as MPA help protect the lining of the uterus from developing this disorder.

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

Your doctor may have prescribed it for another use.

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

Premia Continuous is not habit-forming.

Premia Continuous 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.

Before you take Premia Continuous

When you must not take Premia Continuous

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 Premia Continuous to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated 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 (MPA).

The Women's Health Initiative Memory Study indicated 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 Premia Continuous.

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 Premia Continuous if you have an allergy to:

- Any medicine containing conjugated oestrogens or MPA, the active ingredients in Premia Continuous
- Any of the ingredients listed at the end of this leaflet
- Any other similar medicines containing oestrogen or progestogen, 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 Premia Continuous 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, talk to your doctor.

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

Pregnancy must be excluded before you take Premia Continuous.

Do not take Premia Continuous if you are breast feeding.

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

Do not give this medicine to a child.

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 Premia Continuous

You must have a thorough medical check-up before starting Premia Continuous 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 oestrogens (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 the lungs, a stroke or heart attack.

Taking Other Medicines

Tell your doctor if you are taking birth control pills.

Premia Continuous is not a contraceptive. Since pregnancy may be possible early in 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 Premia Continuous 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
- Antifungal 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
- Aminoglutethemide used to treat breast cancer and a disease called Cushing's syndrome.

Grapefruit juice may also affect how well Premia Continuous works.

If you have not told your doctor about any of the above, tell them before you start taking Premia Continuous

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

How to take Premia Continuous

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 label, ask your doctor or pharmacist for help.

How to take it

Swallow tablets whole with a full glass of water.

When to take Premia Continuous

If you are not already using any type of HRT you can start Premia Continuous on any convenient day. However, it is recommended you start Premia Continuous after your last period. If you do not have predictable periods, then start Premia Continuous 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 Premia Continuous.

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

How much to take

Treatment consists of a 28-day cycle.

Take one tablet daily.

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 it

If less than 12 hours has passed from the time you normally take Premia Continuous, 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 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 Premia Continuous.

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.

While you are taking Premia Continuous

Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking Premia Continuous.

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

If you become pregnant while taking Premia Continuous, tell your doctor immediately.

Premia Continuous 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 fats, sugar levels and liver function.

This helps to monitor for 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 Premia Continuous.

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 Premia Continuous.

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 Premia Continuous 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 Premia Continuous without checking with your doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking Premia Continuous.

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 Premia Continuous 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, pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and 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, secretions from the breasts
- Period-like 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.

After taking Premia Continuous

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 Premia Continuous, or any medicine, in a bathroom or near a sink. Do not leave Premia Continuous 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 Premia Continuous Tablets, or the expiry date has passed, ask your pharmacist what to do with any left over medicine.

Product Description

What it looks like

Premia Continuous tablets are available in two different strengths:

- Premia 2.5 Continuous tablets
- Premia 5 Continuous tablets

Each strength comes in a blister pack containing 28 tablets.

Ingredients

The active ingredients are conjugated oestrogens and MPA.

Each peach, oval Premia 2.5 Continuous Tablet contains conjugated oestrogens 0.625 mg and

MPA 2.5 mg, and is printed with "0.625/2.5" in black ink.

Each blue, oval Premia 5 Continuous Tablet contains conjugated oestrogens 0.625 mg and MPA 5 mg and is printed with "0.625/5" in black ink.

The following inactive ingredients are also found in Premia 2.5 Continuous and Premia 5 Continuous:

- Lactose
- Methylcellulose
- Microcrystalline cellulose
- Povidone
- Sucrose
- Magnesium stearate
- Calcium phosphate
- Calcium sulfate
- Glyceryl mono-oleate
- Macrogol 20000
- Shellac
- Stearic acid
- Titanium dioxide
- Carnauba wax
- Black Ink.

The colouring agent found in Premia 2.5 Continuous is ferric oxide (red) (CI 77491).

The colouring agent found in Premia 5 Continuous is indigo carmine (CI 73015).

Manufacturer

Premia Continuous Tablets are supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll free number: 1800 675 229

Premia Continuous Tablets are supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland

New Zealand

Toll Free number: 0800736363

Australian Registration Numbers:

Premia 2.5 Continuous

AUST R 59300

Premia 5 Continuous

AUST R 59299

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