

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 provide.

If you have any concerns about using Premia Continuous, 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 Premia Continuous

Do not use Premia or other oestrogens, with or without a progestogen 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 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 Premia Continuous.

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

What Premia Continuous is used for

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

Premia Continuous 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. Premia Continuous is used by women who still have a uterus (womb).

If your doctor thinks you will need to take HT for a long time, including for the prevention of osteoporosis, your doctor will have considered the benefits and risks of other treatments before prescribing Premia Continuous 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.

Medroxyprogesterone acetate (MPA) is a hormone called a progestogen. It has effects similar to the female hormone, progesterone, which your ovaries also produced before the 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 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.

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

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

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

Before you take Premia Continuous

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 Premia Continuous if you have an allergy to:

- Conjugated oestrogens or MPA, the active ingredients in Premia Continuous
- Any of the ingredients listed at the end of this leaflet
- Any other medicine containing oestrogen or progestogen, 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 Premia Continuous 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 Premia Continuous 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 Premia Continuous 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.

Premia Continuous is not for use in children.

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

Before you start to take it

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

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 and 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 using Premia Continuous.

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 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 Premia Continuous 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 and erythromycin
- Thyroid replacement therapy
- Dexamethasone
- Aminoglutethemide.

Premia Continuous may affect these medicines or they may affect how well it works. You may need to take

different amounts of your medicines or take different medicines.

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

How to Take Premia Continuous

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 Premia Continuous on any convenient day.

If you are already using a different type of HT, your doctor can advise you when to start Premia Continuous.

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.

Swallow the tablets whole with a glass of water.

Premia Continuous can be taken with a meal or between meals.

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 Premia Continuous.

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

Your doctor can discuss the risks and benefits of long-term treatment with HT in your particular case. Some recent studies have shown that

women using HT have a small increase in breast cancer risk after several years of use. 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.

Recent studies have also shown that HT is associated with a small increase in the risk of heart attacks, strokes, blood clots, including clots in the lungs. On the other hand the risk of hip fractures and bowel cancer 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 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 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 Premia Continuous.

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 breakthrough bleeding.

While you are taking Premia Continuous

Things you must do

If you become pregnant while using Premia Continuous, 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 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 this is happening.

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

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

Things you must not do

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

Do not give Premia Continuous 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 Premia Continuous.

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.
- Bloody diarrhoea, 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.

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

Tell you doctor if you notice any of the following:

- Irregular vaginal 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
- 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 Premia Continuous

Storage

Keep your Premia Continuous Tablets below 25°C.

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

Do not leave Premia Continuous in the car or on windowsills.

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

Heat and dampness can destroy some medicines.

Keep Premia Continuous 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 Premia Continuous Tablets ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

Premia 2.5 Continuous comes in a blister pack containing 28 peach oval tablets printed with "0.625/2.5" in black ink.

Premia 5 Continuous comes in a blister pack containing 28 blue oval tablets printed with "0.625/5" in black ink.

Ingredients

The active ingredients are conjugated oestrogens and MPA.

Each Premia 2.5 Continuous Tablet contains conjugated oestrogens 0.625 mg and MPA 2.5mg.

Each Premia 5 Continuous Tablet contains conjugated oestrogens 0.625 mg and MPA 5mg.

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 following colouring agent is found in Premia 2.5 Continuous:

- Ferric Oxide (red) (CI 77491).

The following colouring agent is found in Premia 5 Continuous:

- Indigo carmine (CI 73015).

Manufacturer

Premia Continuous Tablets are supplied in Australia 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 Premia Continuous call Wyeth on free call:

1800 500 498 (Australia) or email: medinfo@wyeth.com

Australian Registration Numbers:

Premia 2.5 Continuous

AUST R 59300

Premia 5 Continuous

AUST R 59299

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