

PROMETRIUM 100 and 200 mg

Progesterone (micronised) 100 and 200 mg, soft capsule
(For oral use)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prometrium.

The leaflet does not contain all 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 Prometrium against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Prometrium is used for

Prometrium is provided as a soft capsule that contains the natural female hormone, progesterone for oral use.

Prometrium is for women for the treatment of menstrual abnormalities or secondary amenorrhoea (no menstrual periods) and as hormone replacement therapy (HRT) in combination with estrogen in postmenopausal women with an intact uterus (womb).

Your doctor may have prescribed Prometrium for another purpose. Ask your doctor if you have any questions why this medicine has been prescribed for you.

Prometrium is available only with a doctor's prescription.

This medicine is not addictive.

This medicine is not a contraceptive.

Before you take Prometrium

When you must not take it

Do not take Prometrium if you have an allergy to:

- any medicine containing progesterone
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing

Do not take Prometrium if you have or have had any of the following conditions:

- if you are allergic to soya
- unusual vaginal bleeding that has not been evaluated by your doctor
- known missed abortions or ectopic pregnancy
- severe liver problems
- known or suspected cancer of the breast or genital tract
- blood clots (thrombophlebitis or thromboembolic disorder), such as inflammation of a vein, deep vein blood clotting (thrombosis) or a blood clot that travelled to the lungs (pulmonary embolism)
- bleeding on the brain

- porphyria disorder (a blood disease)

Do not take Prometrium if you are pregnant or intend to become pregnant.

If you get pregnant while taking Prometrium, stop taking it straight away and tell your doctor.

Do not take Prometrium if you are breast-feeding.

Do not give Prometrium to a child of any age.

Do not take Prometrium after the expiry date printed on the pack.

Do not take Prometrium if the packaging is torn, shows signs of tampering, or if the product does not look quite right.

If it has expired or if the packaging is damaged, return it to your pharmacist or doctor for disposal.

If you are not sure whether you should start taking Prometrium talk to your doctor.

Before you start to take it

Before starting or recommencing progesterone therapy, a physical examination should have been performed including special attention to the breasts, abdomen and pelvic organs.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

You must tell your doctor or pharmacist if you have or have had any of the following problems:

- epilepsy
- migraine
- high blood pressure

- asthma
- heart, liver or kidney disease
- diabetes
- skin sensitive to light
- history of depression.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Prometrium.

Tell your doctor if you have or have had any of the following problems, before you start treatment, as these may return during treatment with HRT. If so you should see your doctor more often for check-ups:

- fibroids in side your womb,
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots
- increased risk of getting estrogen-sensitive cancer (such as a mother, sister or grandmother who has breast cancer
- gallstones
- severe headaches
- a disease affecting the eardrum and hearing (otosclerosis)
- fluid retention due to cardiac or kidney problems

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Some medicines may interfere with progesterone if taken at the same time. These include:

- Carbamazepine, Phenobarbital and Phenytoin (medicines for epilepsy)
- Rifampicin
- Phenylbutazone

- Spironolactone
- Griseofulvin
- Some antibiotics including ampicillins and tetracyclines
- Bromocriptine
- Ciclosporin
- Ketoconazole

These medicines may be affected by Prometrium or may affect how well they work. You may need different amounts of your medicine or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Prometrium.

How to take Prometrium

How much to take

Your doctor or pharmacist will tell you how many capsules you need to take each day.

For women receiving hormone replacement therapy in conjunction with estrogen with an intact uterus (womb), the usual dose is 200 mg/day at bedtime on days 15 to 26 of your cycle. You will usually have a few days withdrawal bleeding (like a period) after this time. Alternatively 100 mg can be taken at bedtime, from days 1 to 25 of each cycle, withdrawal bleeding being less with this treatment schedule.

For women with secondary amenorrhoea (no menstrual periods), the treatment may be taken as a single daily dose of 400 mg at bedtime, for 10 days.

The standard daily dose is 200 to 300 mg of progesterone taken in one or two doses (i.e. 200 mg in the evening and another 100 mg in the morning, if needed).

In menstrual irregularities due to ovulation disorders, treatment is

administered over 10 days per menstrual cycle, usually from days 17 to 26 inclusive.

Prometrium is to be taken by mouth and swallowed whole with a glass of water.

Do not take Prometrium with food as this may affect the way Prometrium works.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How long to take it

The length of use of Prometrium will differ depending on the intended use and dose prescribed. Prometrium at a dose of 200 mg in conjunction with estrogen as hormone replacement therapy may be taken for up to 12 days in the last half of the cycle or alternately at a dose of 100 mg each day for up to 25 days of the cycle.

In women with secondary amenorrhoea, Prometrium may be continued for up to 10 days.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to, as usual.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

If you are not sure what to do, talk to your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think

that you or anyone else may have taken too much Prometrium. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose with Prometrium include feeling dizzy or feeling tired.

While you are taking Prometrium

Things you must do

Tell any other doctors or pharmacists who are treating you that you are taking Prometrium.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking Prometrium.

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even a few days after the last dosage:

- pains in your calves or chest, a sudden shortness of breath or coughing up blood indicating possible clots in the legs, heart or lungs
- severe headache or vomiting, dizziness, faintness or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye
- worsening symptoms of depression.

Things you must not do

Do not give Prometrium to anyone else, even if they have the same condition as you.

Do not take Prometrium to treat any other complaints unless your doctor has told you to.

Do not stop taking Prometrium or lower the dosage without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Prometrium affects you.

Some people may experience drowsiness or dizziness. Make sure you know how you react to Prometrium before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

Side effects

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

Prometrium helps most people but it may have unwanted side effects in a few people.

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

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

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

- headache
- abnormal breakthrough bleeding and/or vaginal bleeding or spotting or changes in cervical secretions
- any significant change in your menstrual cycle, including loss of menstruation
- Unusual tiredness or weakness or weight gain
- Acne, breast pain or tenderness,
- Mild mood changes, changes in libido and insomnia

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- constipation
- breast disorders (e.g. breast pain, breast swelling and breast tenderness)
- headache, dizziness and drowsiness
- mental depression
- skin rash, itchiness (pruritus)

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Prometrium and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Migraine
- Loss of or change of speech, coordination or vision, pain or numbness in chest, arm or leg; unexplained shortness of breath, any symptoms of blood clots (thrombosis)
- Yellowing of skin or eyes (jaundice)
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Hives

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

After taking Prometrium

Storage

Keep this medicine in its original packaging until it is time to take them.

Keep this medicine in a cool dry place where the temperature stays below 30°C. DO NOT REFRIGERATE.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that are left over.

Product description

What it looks like

Prometrium 100 mg, soft capsule is a round, slightly yellow soft capsule, containing a whitish oily suspension. Prometrium 100 mg, soft capsule is supplied in blister strips packaged in an outer carton. Each carton contains 14, 15, 28, 30, 56, 84 or 90 capsules*.

Prometrium 200 mg, soft capsule is an ovoid slightly yellow soft capsule, containing a whitish oily suspension. Prometrium 200 mg, soft capsule is supplied in blister strips packaged in an outer carton. Each carton contains 7, 14, 15, 21, 28, 30 (trade and starter pack), 42, 45, 56, 84 or 90* capsules.

* Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- progesterone 100 mg or 200 mg

Inactive ingredients:

- sunflower oil
- soya lecithin
- gelatin
- glycerol
- titanium dioxide

Sponsor

Prometrium is supplied in Australia by:

Besins Healthcare Australia Pty Ltd,
Level 16, Tower 2, Darling Park,
201 Sussex Street, Sydney,
NSW 2000

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AUST R 232823