Prometrium (Utrogestan)

Why is this drug prescribed?
Prometrium is prescribed for postmenopausal women who are taking estrogen (hormone replacement therapy); it prevents a buildup of the lining of the uterus and abnormal bleeding. Prometrium also may be prescribed to restore menstruation if your menstrual periods have stopped.

Most important fact about this drug
Prometrium increases the risk of blood clots, which can lead to phlebitis, breathing problems, vision problems, or stroke. If you experience any symptoms that might suggest the onset of a clot-related disorder—pain with swelling, warmth, and redness in a leg vein, coughing or shortness of breath, loss of vision or double vision, migraine, or weakness or numbness in an arm or leg—stop taking Prometrium and see your doctor immediately.

How should you take this medication?
Take Prometrium as directed by your doctor. If Prometrium is prescribed to prevent abnormal buildup of the uterine lining, you will take it once a day for 12 days in a 28-day cycle. If it is prescribed to treat missed menstrual periods, you will take it for 10 days. Prometrium is taken in the evening.

--If you miss a dose...
Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Never take 2 doses at the same time.

--Storage instructions...
Store at room temperature. Protect from light and moisture.

What side effects may occur?
Side effects cannot be anticipated. If any develop or change in
intensity, inform your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking Prometrium.

- **More common side effects may include:**
  Abdominal cramping, back pain, bloating, breast tenderness or pain, chest pain, constipation, coughing, depression, diarrhea, dizziness, emotional instability, fatigue, headache, hot flashes, irritability, joint pain, muscle pain, nausea, night sweats, swelling of hands and feet, upper respiratory infection, urinary problems, vaginal discharge, vaginal dryness, viral infection, vomiting, worry

- **Less common or rare side effects may include:**
  Abnormal vision, acne, abscess, allergic reaction, anxiety, arthritis, blood clot, breakthrough bleeding (between menstrual periods), breast cancer or lump, breast enlargement, bronchitis, change in menstrual flow, chest pain, confusion, decreased or increased appetite, dry mouth, earache, fever, fibroids in uterus, gallbladder disorder, herpes simplex, high blood pressure, indigestion, injury, insomnia, irregular heartbeat, itching, lack of menstruation, leg cramps, lung inflammation, lymph problems, muscle tension, nasal congestion, nervousness, personality disorder, rash, rectal bleeding, sleepiness, sinus inflammation, skin discoloration, sore throat, stomach or intestinal inflammation, speech disorder, spotting, stomach hernia, swelling, throat infection, tooth disorders, vaginal inflammation, warts, weakness, weight change, yellowed skin and eyes

### Why should this drug not be prescribed?

Do not take Prometrium if you have ever had an allergic reaction to it. Prometrium contains peanut oil, so you should also avoid this medication if you are allergic to peanuts.

Do not take Prometrium if you are pregnant or have had an incomplete miscarriage. Avoid it if you have ever had a blood clotting disorder or a stroke. Do not take this drug if you have breast or genital cancer, unexplained vaginal bleeding, or severe liver disease.

### Special warnings about this medication

To rule out cancer and other problems before you start taking Prometrium, your doctor will give you a complete physical exam, including examination of your breasts and pelvic organs. You also
should have a Pap test (cervical smear). Tell your doctor if you experience any irregular vaginal bleeding while taking this medication.

Remember that Prometrium can cause clot-related disorders. Check with your doctor immediately if you experience any of the warning signs listed in "Most important fact about this drug."

Prometrium may cause some degree of fluid retention. If you have a medical condition that could be made worse by fluid retention--such as epilepsy, migraine, asthma, or a heart or kidney problem--make sure your doctor knows about it.

Prometrium makes some women depressed. If you've suffered from serious depression in the past, alert your doctor if you think you're having a relapse You will probably need to stop taking Prometrium.

Prometrium has a slight effect on insulin and blood sugar levels. If you have diabetes, your doctor will want to watch you closely while you are taking this drug.

Prometrium may make you dizzy or drowsy. Do not drive or operate machinery until you know how this medication affects you. If you experience extreme drowsiness or dizziness, the doctor may tell you to take Prometrium at bedtime.

Because progesterone is processed in the liver and kidneys, the doctor will monitor you closely if you have a mild liver or kidney disorder. If you have severe liver disease, the drug should not be used at all.

In rare cases, women taking Prometrium suffer a sudden drop in blood pressure that can cause them to faint.

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**Possible food and drug interactions when taking this medication**

Tell the doctor if you're taking the antifungal medication ketoconazole (Nizoral) or a similar drug. It's possible that it may increase Prometrium's effect.

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**Special information if you are pregnant or breastfeeding**
Because the possibility of harm to a developing infant cannot be ruled out, Prometrium should not be taken during pregnancy.

Prometrium appears in breast milk. The drug is recommended for nursing mothers only if it is clearly necessary.

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**Recommended dosage**

**ADULTS**

*To Prevent Abnormal Buildup of the Uterine Lining*

For women taking daily conjugated estrogen tablets, the usual dosage of Prometrium is 200 milligrams taken each evening for 12 days in a 28-day cycle.

*To Restore Menstrual Periods*

The usual dose is 400 milligrams taken each evening for 10 days.

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**Overdosage**

Although no specific information is available, any medication taken in excess can have serious consequences. If you suspect an overdose of Prometrium, seek medical attention immediately.