

## PATIENT INFORMATION

Micronized  
**Prometrium**<sup>®</sup>  
PROGESTERONE, USP  
Capsules

500033 Rev Dec 2004  
(Updated 01 Dec 2004)

PROMETRIUM<sup>®</sup> (progesterone, USP)  
Capsules 100 mg  
Capsules 200 mg

Rx only

Read this PATIENT INFORMATION before you start taking PROMETRIUM<sup>®</sup> Capsules and read what you get each time you refill PROMETRIUM Capsules, because there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PROMETRIUM CAPSULES (A Progesterone Hormone)?

Progesterone with or without estrogens should not be used to prevent heart attacks or heart disease.

Using estrogens with or without progestins may increase your chances of getting heart attacks, strokes, breast cancer, and blood clots. Using estrogens with progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with PROMETRIUM Capsules.

### THIS PRODUCT CONTAINS PEANUT OIL AND SHOULD NOT BE USED IF YOU ARE ALLERGIC TO PEANUTS.

#### What is PROMETRIUM Capsules?

PROMETRIUM Capsules contain the female hormone called progesterone.

#### What is PROMETRIUM Capsules used for?

##### *Treatment of Menstrual Irregularities*

PROMETRIUM Capsules are used for the treatment of secondary amenorrhea (absence of menstrual periods in women who have previously had a menstrual period) due to a decrease in progesterone. When you do not produce enough progesterone, menstrual irregularities can occur. If your healthcare provider has determined your body does not produce enough progesterone on its own, PROMETRIUM Capsules may be prescribed to provide the progesterone you need.

##### *Protection of the Endometrium (Lining of the Uterus)*

PROMETRIUM Capsules are used in combination with estrogen-containing medications in postmenopausal women with a uterus. Taking estrogens alone increases the chance of developing a condition called endometrial hyperplasia, that may lead to cancer of the lining of the uterus. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

#### Who should not take PROMETRIUM Capsules?

Do not start taking PROMETRIUM Capsules if you:

- are allergic to peanuts.
- are allergic to progesterone, progesterone-like drugs, or any of the inactive ingredients in the capsules.

See the end of this leaflet for a list of ingredients in PROMETRIUM Capsules.

- are pregnant or suspect that you are pregnant.
- have or have had blood clots in the legs, lungs, eyes, brain, or elsewhere.
- have liver disease.
- have known or suspected cancer of the breast or reproductive organs.
- have unusual bleeding from the vagina which has not been evaluated by your healthcare provider.
- have a miscarriage and your healthcare provider suspects some tissue is still in the uterus.
- are nursing.

#### Tell your healthcare provider:

- if you are breastfeeding. The hormones in PROMETRIUM Capsules can pass into your milk.
- about all of your medical problems. Your healthcare provider may need to check you more carefully if you have certain conditions, such as diabetes, asthma (wheezing), epilepsy (seizures), migraine, endometriosis, lupus, problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- about all the medicines you take. This includes prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how PROMETRIUM Capsules works. PROMETRIUM Capsules may also affect how your other medicines work.

#### How should I take PROMETRIUM Capsules?

1. Prevention of Endometrial Hyperplasia: Postmenopausal women with a uterus who are taking estrogens should take a single daily dose of 200 mg PROMETRIUM Capsules at bedtime for 12 continuous days per 28-day cycle.
2. Secondary Amenorrhea: PROMETRIUM Capsules may be given as a single daily dose of 400 mg at bedtime for 10 days.
3. PROMETRIUM Capsules are to be taken at bedtime as some women become very drowsy\* and/or dizzy\* after taking PROMETRIUM Capsules. In a small percentage of these women, these effects may be increased including blurred vision, difficulty speaking, difficulty walking, and feeling abnormal. If you experience these symptoms, discuss them with your healthcare provider immediately. Taking PROMETRIUM Capsules at bedtime may minimize the impact of these symptoms.

\*Use caution when driving a motor vehicle or operating machinery as dizziness or drowsiness may occur.

If you experience difficulty in swallowing PROMETRIUM Capsules, it is recommended that you take your daily dose at bedtime with a glass of water while in the standing position.

#### What are the risks associated with PROMETRIUM Capsules?

- **Risk to the Fetus:** Rare cases of cleft palate, cleft lip, and congenital heart defects have been reported in the infants of women using PROMETRIUM Capsules during early pregnancy. Although it is not clear that these events were drug related, you should check with your healthcare provider about the risks to your unborn child of any medication taken during pregnancy.
- **Abnormal Blood Clotting:** Use of progestational drugs has been associated with changes in the blood-clotting system. These changes allow the blood to clot more easily, possibly allowing clots to form in the bloodstream. If blood clots do form in your bloodstream, they can cut off the blood supply to vital organs, causing serious problems. These problems may include a stroke (by cutting off blood to part of the brain), a heart attack (by cutting off blood to part of the heart), a pulmonary embolus (by cutting off blood to part of the lungs), visual loss or blindness (by cutting off blood vessels in the eye), or

other problems. Any of these conditions may cause death or serious long-term disability. Call your healthcare provider immediately if you suspect you have any of these conditions. He or she may advise you to stop using this drug.

- **Eye Abnormalities:** Discontinue medication and call your healthcare provider immediately if you experience sudden partial or complete loss of vision, blurred vision, or sudden onset of bulging eyes, double vision, or migraine.

#### **What are the possible side effects of PROMETRIUM Capsules?**

Consult your healthcare provider if you experience any of the side effects mentioned below or other side effects.

SIDE EFFECTS REPORTED IN STUDIES OF PATIENTS AT DOSES OF 100 MG/DAY to 400 MG/DAY:

**Blood and Lymphatic System:** swelling of the lymph nodes

**Cardiovascular System:** high blood pressure, hot flashes, pounding or racing of the heart

**Digestive System:** bloating, constipation, diarrhea, dry mouth, heartburn, indigestion, nausea/vomiting

**General Disorders:** abdominal pain (cramping), back pain, chest pain, fatigue, fever, fluid retention, headache, intestinal pain, stomach pain, swelling, swelling of the legs and arms

**Infections:** bronchitis, fungal vaginal infection, infections, inflammation of the vagina, upper respiratory tract infection, urinary tract infection, viral infection

**Musculoskeletal System:** arthritis, joint pain, muscle or bone pain, leg cramps, muscle cramps

**Nervous/Psychiatric System:** anxiety, confusion, decreased concentration, depression, dizziness\*, drowsiness\*, irritability, mood swings, personality disorder, sleep disorder, worry

**Respiratory System:** coughing, fluid in sinus cavities, nasal congestion, sore throat, fluid in the lungs

**Reproductive System:** breast pain, breast tenderness, vaginal discharge, vaginal dryness, uterine fibroid

**Skin:** acne, night sweats

**Eyes:** blurred vision

**Kidney and Urinary System:** urinary problems

\*Use caution when driving a motor vehicle or operating machinery as dizziness or drowsiness may occur.

During the marketing of PROMETRIUM Capsules, other adverse events have been reported, including reversible cases of liver problems, particularly in patients taking high doses. Additionally, rare occurrences of fainting and/or low blood pressure have also been reported.

#### **These are some of the warning signs of serious side effects:**

Be alert for unusual signs and symptoms. If any of these warning signals (or any other unusual symptoms) happen while you are using PROMETRIUM Capsules, call your healthcare provider immediately:

- Breast lumps (Ask your healthcare provider to show you how to examine your breasts monthly.)
- Pain, swelling, or tenderness in the abdomen
- Tremors or seizures, migraine headaches, shortness of breath or asthma, heart problems, or kidney problems
- Abnormal bleeding from the vagina
- Feelings of depression
- Pains in the calves or chest; a sudden shortness of breath; or coughing blood, indicating possible clots in the legs, heart or lungs
- Severe headache, vomiting, dizziness, faintness, or changes in vision or speech; weakness or numbness in an arm or leg, indicating possible clots in the brain or eye

#### **General information about safe and effective use of PROMETRIUM Capsules**

- Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take PROMETRIUM Capsules for conditions for which it was not prescribed.
- Your healthcare provider has prescribed this drug for you and you alone. Do not give PROMETRIUM Capsules to other people, even if they have the same symptoms you have. It may harm them.
- PROMETRIUM Capsules should be taken as a single daily dose at bedtime. Some women may experience extreme dizziness and/or drowsiness during initial therapy. In a small percentage of women, these effects may be increased including blurred vision, difficulty speaking, difficulty walking, and feeling abnormal. If you experience these symptoms, discuss them with your healthcare provider immediately. A single bedtime dose may reduce the impact of these symptoms.
- Use caution when driving a motor vehicle or operating machinery as dizziness or drowsiness may occur.

#### **Keep PROMETRIUM Capsules out of the reach of children.**

This leaflet provides a summary of the most important information about PROMETRIUM Capsules. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about PROMETRIUM Capsules that is written for health professionals. You can get more information by calling the toll free number 1-800-241-1643.

#### **What are the ingredients in PROMETRIUM Capsules?**

Active ingredient: 100 mg or 200 mg micronized progesterone

The inactive ingredients for PROMETRIUM Capsules 100 mg include: peanut oil NF, gelatin NF, glycerin USP, lecithin NF, titanium dioxide USP, D&C Yellow No. 10, and FD&C Red No. 40.

The inactive ingredients for PROMETRIUM Capsules 200 mg include: peanut oil NF, gelatin NF, glycerin USP, lecithin NF, titanium dioxide USP, D&C Yellow No. 10, and FD&C Yellow No. 6.

#### **HOW SUPPLIED**

PROMETRIUM Capsules 100 mg are round, peach-colored capsules branded with black imprint "SV."

PROMETRIUM Capsules 200 mg are oval, pale yellow-colored capsules branded with black imprint "SV2."

**Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].**

**Protect from excessive moisture.**

#### **Manufactured by:**

Cardinal Health Encapsulation Technologies  
St. Petersburg, FL 33716

#### **Marketed by:**

Solvay Pharmaceuticals, Inc.  
Marietta, GA 30062  
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