

## **PATIENT INFORMATION**

### **PROMETRIUM® (progesterone, USP)**

**Capsules 100 mg**

**Capsules 200 mg**

Read this PATIENT INFORMATION before you start taking PROMETRIUM Capsules and read what you get each time you refill your PROMETRIUM Capsules prescription. 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.

<b>WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PROMETRIUM CAPSULES (A Progesterone Hormone)?</b>
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| <ul style="list-style-type: none"><li>• Progestins with estrogens should not be used to prevent heart disease, heart attacks, strokes, or dementia.</li><li>• Using progestins with estrogens may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots.</li><li>• Using progestins with estrogens may increase your chance of getting dementia, based on a study of women age 65 and older.</li><li>• You and your healthcare provider should talk regularly about whether you still need treatment with PROMETRIUM Capsules.</li></ul> |
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**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 a postmenopausal woman with a uterus (womb). Taking estrogen-alone increases the chance of

developing a condition called endometrial hyperplasia that may lead to cancer of the lining of the uterus (womb). The addition of a progestin is generally recommended for a woman with a uterus to reduce the chance of getting cancer of the uterus (womb).

### **Who should not take PROMETRIUM Capsules?**

Do not start taking PROMETRIUM Capsules if you:

- **Are allergic to peanuts**
- **Have unusual vaginal bleeding**
- **Currently have or have had certain cancers**  
Estrogen plus progestin treatment may increase the chance of getting certain types of cancers, including cancer of the breast or uterus. If you have or have had cancer, talk with your healthcare provider about whether you should take PROMETRIUM Capsules.
- **Had a stroke or heart attack**
- **Currently have or have had blood clots**
- **Currently have or have had liver problems**
- **Are allergic to PROMETRIUM Capsules or any of its ingredients**

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

- **Think you may be pregnant**

### **Tell your healthcare provider:**

- **If you are breastfeeding.** The hormone in PROMETRIUM Capsules can pass into your breast milk.
- **About all of your medical problems.** Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, problems with your heart, liver, thyroid, or 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 work. PROMETRIUM Capsules may also affect how your other medicines work.

## How should I take PROMETRIUM Capsules?

1. Prevention of Endometrial Hyperplasia: A postmenopausal woman with a uterus who is 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 few cases, symptoms may include blurred vision, difficulty speaking, difficulty with walking, and feeling abnormal. If you experience these symptoms, discuss them with your healthcare provider right away.**
4. 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 possible side effects of PROMETRIUM Capsules?

Side effects are grouped by how serious they are and how often they happen when you are treated:

### **Serious, but less common side effects include:**

- ***Risk to the Fetus:*** Cases of cleft palate, cleft lip, hypospadias, ventricular septal defect, patent ductus arteriosus, and other congenital heart defects.
- ***Abnormal Blood Clotting:*** Stroke, heart attack, pulmonary embolus, visual loss or blindness.

### **Some of the warning signs of serious side effects include:**

- Changes in vision or speech
- Sudden new severe headaches
- Severe pains in your chest or legs with or without shortness of breath, weakness and fatigue
- Dizziness and faintness
- Vomiting

Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptoms that concern you.

**Less serious, but common side effects include:**

- Headaches
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach or abdominal cramps, bloating
- Nausea and vomiting
- Hair loss
- Fluid retention
- Vaginal yeast infection

These are not all the possible side effects of PROMETRIUM Capsules. For more information, ask your healthcare provider or pharmacist for advice about side effects. You may report side effects to AbbVie Inc. at 1-800-633-9110 or to FDA at 1-800-FDA-1088.

**What can I do to lower my chances of getting a serious side effect with PROMETRIUM Capsules?**

- Talk with your healthcare provider regularly about whether you should continue taking PROMETRIUM Capsules.
- See your healthcare provider right away if you get unusual vaginal bleeding while taking PROMETRIUM Capsules.
- Have a pelvic exam, breast exam, and mammogram (breast X-ray) every year unless your healthcare provider tells you something else. If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often.
- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease. Ask your healthcare provider for ways to lower your chances for getting heart disease.

**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 few cases, symptoms may include blurred vision, difficulty speaking, difficulty with walking, and feeling abnormal. If you experience these symptoms, discuss them with your healthcare provider right away.
- 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 1-800-633-9110.

**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, FD&C Red No. 40, and D&C Yellow No. 10.

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:**

Catalent Pharma Solutions

St. Petersburg, FL 33716

**Marketed by:**

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