

## **PATIENT INFORMATION**

(Updated 1/18/2008)

### **Progesterone**

Read this Patient Information leaflet before you start taking progesterone and read what you get each time you refill your progesterone prescription. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

#### **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PROGESTERONE?**

- Progesterone with or without estrogens should not be used to prevent heart attacks or heart disease.
- Using estrogens with or without progesterone may increase your chances of getting heart attacks, strokes, breast cancer, and blood clots.
- Using estrogens with

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

#### **What is progesterone?**

Progesterone is a naturally occurring female hormone. This medication is derived from wild yams.

#### **What is progesterone used for?**

- **Treatment of Menstrual Irregularities**

Progesterone is 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, Progesterone may be prescribed to provide the progesterone you need.

Progesterone 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 progesterone is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

#### **Who should not take progesterone?**

Do not start taking progesterone if you:

- **Are allergic to progesterone, progesterone-like drugs, or any of the inactive ingredients in your compound (you may ask the pharmacist for a list of inactive ingredients)**
- **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.** Progesterone 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 progesterone works.
- Progesterone may also affect how your other medicines work.

#### **How should I take Progesterone?**

1. Start at the lowest dose and talk to your health care provider about how well that dose is working for you.
2. Progesterone should be used at the lowest dose possible for your treatment only as long as needed. You and your health care provider should talk regularly (e.g., every 3 to 6 months) about the dose you are taking and whether you still need treatment with progesterone.
3. Progesterone can be compounded in many different dosage forms, including oral capsules, troches, topical creams/gels applied to the skin or vaginal area.
  - a. Oral preparations may be taken with or without food.
  - b. Troche preparations should be dissolved under the tongue or in the cheek. It should dissolve in 10-15 minutes. Do not eat or drink anything for 10-15 minutes after and brush your teeth before going to bed.

- c. Topical preparations should be applied to the area or inserted as indicated on the prescription label or as directed by your health care provider. Make sure to wash hands before and after each use. Measure dose indicated on prescription label using the syringe or measuring device provided.
4. Progesterone may cause drowsiness therefore is usually taken in the evening or at bedtime. Some women become very drowsy and/or dizzy after taking progesterone. 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 health care provider immediately. Use caution when driving a motor vehicle or operating machinery.
5. Take progesterone at the same time each day.
6. Progesterone may be prescribed in a cyclic fashion on specific days of the cycle. Day 1 is defined as the first day of menstrual flow.

**What do I do in case of an overdose/emergency?**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222 or the Arizona Poison Control Center at 520-626-6016.

**What should I do if I forget a dose?**

If you miss a dose do not double the dose on the next day to catch up. If your next dose is less than 12 hours away, skip the missed dose and go back to your regular dosing schedule. If it is more than 12 hours until the next dose, take the dose you missed and resume your normal dosing the next day.

**What storage conditions are needed for this medication?**

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture; excursions permitted to 59-86 degrees F (15-30 degrees C). [see USP Controlled Room Temperature]. Do not store in bathroom, the car or expose to heat.

**What are the risks associated with Progesterone?**

- **Risk to the Fetus:** Rare cases of cleft palate, cleft lip, and congenital heart defects have been reported in the infants of women using progesterone 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 Progesterone?**

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

In rare circumstances, 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 progesterone, 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 progesterone**

- Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take Progesterone for conditions for which it was not prescribed.
- Your healthcare provider has prescribed this drug for you and you alone. Do not give Progesterone to other people, even if they have the same symptoms you have. It may harm them.
- Progesterone is usually taken 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 Progesterone out of the reach of children and pets.**

This leaflet provides a summary of the most important information about progesterone. If you would like more information, talk with your health care provider or pharmacist. You can get more information by speaking to one of our pharmacists directly in person or over the telephone (520-318-4421).