



## PATIENT INFORMATION & EDUCATION

### HORMONE REPLACEMENT THERAPY

#### PROGESTERONE - Micronized

Pronounced (pro-jess-ter-own) - is a female hormone prescribed primarily to protect the lining of the uterus in women on estrogen replacement therapy, both bio-equivalent or natural, and synthetic. Supplemental progesterone therapy may lower the risk of estrogen-related cancer of the uterus. This medication is also prescribed to treat women who have had menstrual periods in the past, but have stopped having periods because of a lack of naturally produced progesterone. This medication may also be prescribed by your doctor to treat other medical conditions that benefit from its use.

#### **DIRECTIONS**

Follow the directions for using this product provided by your doctor and pharmacist. **STORE THIS MEDICATION** at room temperature, or approximately 70 to 77 degrees F (22 to 25 degrees C) in a tightly-closed container, away from heat sources, moisture, and light. Brief storage between 59 and 86 degrees F (15 to 30 degrees C) is permitted during travel or other circumstances. **IF YOU MISS A DOSE OF THIS MEDICATION** and are only taking it at bedtime, apply the missed dose the following morning and then resume your evening dosing schedule. **IF YOU MISS A DOSE OF THIS MEDICATION** and are taking it both in the morning and the evening, skip the missed dose and resume your regularly scheduled morning and evening dosing schedule. **DO NOT** double the dose during your dosing schedule to make up for a missed dose.

#### **PRECAUTIONS**

**DO NOT TAKE THIS MEDICATION** if you have had an allergic reaction to it or are allergic to any ingredient in this product. **THIS MEDICATION MAY CAUSE DROWSINESS OR DIZZINESS. DO NOT DRIVE, OPERATE MACHINERY, OR DO ANYTHING ELSE THAT COULD BE OF DANGER TO YOU OR OTHERS** until you know the effects of this medication and how you react to it. Using this medication in conjunction with other medications or alcohol may lessen your ability to drive, operate machinery, or perform other dangerous tasks.

**DO NOT USE THIS MEDICATION IF YOU ARE PREGNANT, OR SUSPECT YOU ARE PREGNANT** until you consult with your doctor, or instructed by your doctor to take this medication during pregnancy. **THIS MEDICATION IS EXCRETED IN BREAST MILK. IF YOU ARE, OR WILL BE BREAST FEEDING** while using this medication, consult with your physician, pediatrician, and/or pharmacist about potential risks to your baby.

## **FREQUENTLY ASKED QUESTIONS regarding Progesterone**

by John R. Lee, M.D. and Virginia Hopkins

**Q: What is progesterone?**

**A: Progesterone is a steroid hormone made by the corpus luteum of the ovary at ovulation, and in smaller amounts by the adrenal glands. Progesterone is manufactured in the body from the steroid hormone pregnenolone, and is a precursor to most of the other steroid hormones, including cortisol, androstenedione, the estrogens and testosterone.**

**In a normally cycling female, the corpus luteum produces 20 to 30 mg of progesterone daily during the luteal phase of the menstrual cycle.**

**Q: Why do women need progesterone?**

**A: Progesterone is needed in hormone replacement therapy for women for many reasons, but one of its most important roles is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for breast cancer and reproductive cancers.**

**Estrogen levels drop only 40-60% at menopause, which is just enough to stop the menstrual cycle. But progesterone levels may drop to near zero in some women. Because progesterone is the precursor to so many other steroid hormones, its use can greatly enhance overall hormone balance after menopause. Progesterone also stimulates bone-building and thus helps protect against osteoporosis.**

**Q: Why not just use the progestin Provera as prescribed by most doctors?**

**A: Progesterone is preferable to the synthetic progestins such as Provera because synthetics only mimic naturally produced progesterone, but cannot be used by the human body. Bio-Equivalent progesterone is equivalent to the natural progesterone produced by the human body and has no undesirable side effects when used as directed.**

**If you have any doubts about how different progesterone is from the progestins, remember that the placenta produces 300-400 mg of progesterone daily during the last few months of pregnancy, so we know that such levels are safe for the developing baby. But progestins, even at fractions of this dose, can cause birth defects. The progestins also cause many other side effects, including partial loss of vision, breast cancer in test dogs, an increased risk of strokes, fluid retention, migraine headaches, asthma, cardiac irregularities and depression. Because synthetic progestins mimic natural progesterone, the body may actually reduce production of natural progesterone, thereby causing exacerbated estrogen dominance symptoms.**

**Q: What is estrogen dominance?**

**A: Dr. Lee has coined the term "estrogen dominance," to describe what happens when the normal ratio or balance of estrogen to progesterone is changed by excess estrogen or inadequate progesterone. Estrogen is a potent and potentially dangerous hormone when not balanced or offset by adequate progesterone.**

**Both women who have suffered from PMS and women who have suffered from menopausal symptoms, will recognize the hallmark symptoms of estrogen dominance: weight gain, bloating, mood swings, irritability, tender breasts, headaches, fatigue, depression, hypoglycemia, uterine fibroids, endometriosis, and fibrocystic breasts. Estrogen dominance is known to cause and/or contribute to cancer of the breast, ovaries, endometrium (uterus), and prostate in men.**

**Q: Why would a pre-menopausal woman need progesterone cream?**

**A: In the ten to fifteen years before menopause, many women regularly have anovulatory cycles in which they make enough estrogen to create menstruation, but they don't make any progesterone, thus setting the stage for estrogen dominance. Using progesterone cream during anovulatory months can help prevent the symptoms of PMS.**

**We now know that PMS can occur despite normal progesterone levels when stress is present. Stress increases cortisol production; cortisol blockades (or competes for) progesterone receptors. Additional progesterone is required to overcome this blockade, as well, stress management techniques become very important.**

**Q: What is progesterone made from?**

**A: The USP progesterone used for hormone replacement comes from plant fats and oils, usually a substance called diosgenin which is extracted from a very specific type of wild yam that grows in Mexico, or from soybeans. In the laboratory diosgenin is chemically synthesized into real human progesterone. The other human steroid hormones, including estrogen, testosterone, progesterone and the cortisones are also nearly always synthesized from diosgenin.**

**Some companies are trying to sell diosgenin, which they label "wild yam extract" as a medicine or supplement, claiming that the body will then convert it into hormones as needed. While we know this can be done in the laboratory, there is no evidence that this conversion takes place in the human body.**

**Q: Where should I put the progesterone cream?**

**A: Because progesterone is very fat-soluble, it is easily absorbed through the skin. From subcutaneous fat, progesterone is absorbed into capillary blood. Thus absorption is best at all the skin sites where people blush: face, neck, chest, breasts, inner arms and palms of the hands.**

**Q: What is the recommended dosage of progesterone?**

**A: For pre-menopausal women the usual dose is 15-24 mg/day for 14 days before expected menses, stopping the day or so before menses.**

For post-menopausal women, the dose that often works well is 15 mg/day for 25 days of the calendar month.

**Q: What amount of progesterone do you recommend in a cream?**

**A: Dr. Lee recommends the creams that contain 450-500 mg of progesterone per ounce, which is 1.6% by weight or 3% by volume. This means that about ¼ teaspoon daily would provide about 20 mg/day.**

**Q: How safe is progesterone cream?**

**A: During the third trimester of pregnancy, the placenta produces about 300 mg of progesterone daily, so we know that a one-time overdose of the cream is virtually impossible. If you used a whole jar at once it might make you very sleepy. However, Dr. Lee recommends that women avoid using higher than the recommended dosage to avoid hormone imbalances. More is not better when it comes to hormone balance.**

**Q: Wouldn't it be easier to just take a progesterone pill?**

**A: Dr. Lee recommends trans-dermal cream rather than oral progesterone, because some 80% to 90% of the oral dose is lost through the liver. Thus, at least 200 to 400 mg daily is needed orally to achieve a physiologic dose of 15 to 24 mg daily. Such high doses create undesirable metabolites and unnecessarily overload the liver.**

**Q: Where can I get more information on progesterone and natural hormone balance?**

**A: For a detailed explanation of women's hormone balance issues, a hormone balance program, as well as detailed descriptions of how to use natural progesterone, the following books by John R. Lee, M.D. are recommended:**

**What Your Doctor May Not Tell You About Menopause**  
**(Found in the Compounding Specialists of Wyoming Book Store)**  
**John R. Lee, M.D. (Warner Books)**

**This is the classic on natural hormones, and natural progesterone in particular, that every woman should have on her bookshelf. Dr. John Lee covers everything from the politics of menopause to the biochemistry of hormone balance, as well as gives wonderfully down-to-earth advice about diet and exercise. There is an extensive chapter on osteoporosis, help for women with tired adrenals, and detailed instructions on how to use natural progesterone cream. This is a book you will go back to over and over again as a guide and reference.**

**What Your Doctor May Not Tell You About Pre-menopause**  
**(Found in the Compounding Specialists of Wyoming Book Store)**

**John R. Lee, M.D. (Warner Books)**

**No, PMS is not all in your head! And neither are cramps, irregular periods, PCOS, infertility, endometriosis, fatigue and weight gain! Dr. Jesse Hanley joins Dr. Lee and Virginia Hopkins to take the mystery out of hormone imbalances that can disrupt a woman's life in her thirties and forties. Many case histories make this book an easy read, and detailed instructions are provided on how to use progesterone cream, herbs, supplements, diet, exercise and stress management to achieve hormone balance.**

**What Your Doctor May Not Tell You About Breast Cancer: How Hormone Balance Can Help Save Your Life** **(Found in the Compounding Specialists of Wyoming Book Store)**

**John R. Lee, M.D. and David Zava, Ph.D. (Warner Books)**

**Dr. David Zava brings his expertise in breast cancer research to this amazing book, co-authored with the great John R. Lee, M.D. There is no other book on the market that details the underlying mechanisms of breast cancer in a way that is so thorough and accurate yet readable and useful. Did you know that high cortisol or low thyroid can contribute to breast cancer? That changes in diet can change how your body processes estrogen? That natural progesterone balances excess estrogen and may protect you from cell changes that create breast cancer? The authors also tackle tough issues such as why synthetic HRT causes breast cancer, whether mammograms are safe and effective, and whether breast cancer drugs may do more harm than good.**