

Understanding ovulation and avovulation



LAWLEY

Hormone Solutions

Table of Contents

What is ovulation?	1
What is anovulation?	1
What is a normal menstrual cycle?	1
Follicular phase	2
Luteal phase	3
Withdrawal bleeding	3
How can I detect ovulation?	6
How do I calculate blood loss?	6
What causes anovulation?	7
Why is anovulation a problem?	8
Ovulatory changes with age	9
Puberty (approximate age 11-15 years)	9
Young Adulthood (15 – 35 years)	10
Perimenopause (mid 30's onwards)	11
Menopause	12
More serious medical conditions	12
Anemia	13
Menorrhagia	13
Metrorrhagia	14
Menometrorrhagia	14
Endometrial Hyperplasia	14
PMS – Premenstrual Syndrome	16
What is the role of progesterone in humans?	16
Are there side-effects associated with using natural progesterone?	17
What about homeopathic and herbal treatments?	18
How do I use PROFEME® progesterone cream?	19
Why is ProFeme® progesterone cream the best?	22
About Lawley Pharmaceuticals	23
Natural Progesterone for Women – Quick Q & A	25
Our Mission Statement	27
Completed Clinical Studies	28
Internet Education Reference Sites	29
References for Medical Professionals	31
Glossary	33

What is ovulation?

Ovulation occurs when a woman's ovary ejects a ripe egg in readiness for fertilization. Ovulation generally commences within a couple of years after the onset of puberty and occurs monthly until menopause. In a normal 28-day menstrual cycle ovulation occurs about 14 days from the first day of your last menstrual period. At the point of ovulation the follicle (sac surrounding the egg) only breaks open and releases the egg. The egg moves into the fallopian tube (horn of the uterus) and can be fertilized by male sperm within 12-48 hours. If it is not fertilized, it disintegrates. Ovulation disorders cause 25% of infertility in females.

What is anovulation?

Anovulation is when ovulation fails to take place. It is not uncommon for this to happen occasionally during a woman's reproductive lifecycle, however around 10% of women experience anovulation on a regular basis. The failure of the ovary to release a mature egg has a dramatic impact on the production of the hormone progesterone which is only produced if ovulation is successful. As a consequence, this has a disruptive effect on the woman's hormonal balance. Multiple anovulatory cycles generally result in a variety of symptoms which can adversely affect a woman's quality of life, overall general health, fertility and, with time, lead to more severe medical conditions.

What is a normal menstrual cycle?

To properly comprehend ovulation and anovulation it is important to understand normal ovulation and the menstrual cycle. The menstrual cycle is sequence of precisely timed hormonal events that when combined create the environment for pregnancy to occur and develop successfully. The menstrual cycle has three distinct phases

- the follicular phase
- the luteal phase
- the withdrawal bleed

Female babies are born with 2 million immature eggs in the ovaries. With age these eggs degenerate so by the time of puberty girls have around 300,000 eggs remaining. At most, 500 of these eggs will mature during the menstrual cycles between puberty and menopause.

Follicular phase

The first part of the menstrual cycle is called the follicular phase, when an egg ripens in a follicle of your ovary and the tissue cells lining of the wall of the uterus (**endometrium**) multiply and grow in preparation to receive a fertilized egg (proliferative endometrium). Ovulation should occur around Day 13 to 15 of a standard 28-day cycle. Estrogen rises at the start of the fertile period, and luteinizing hormone (LH) rises 24-36 hours before the egg is released. The breasts may be tender and your cervix (the area where the top of the vaginal passage joins the uterus) will soften, rise, and open slightly. Having intercourse daily during the mid-cycle fertile period will maximize the likelihood of pregnancy.

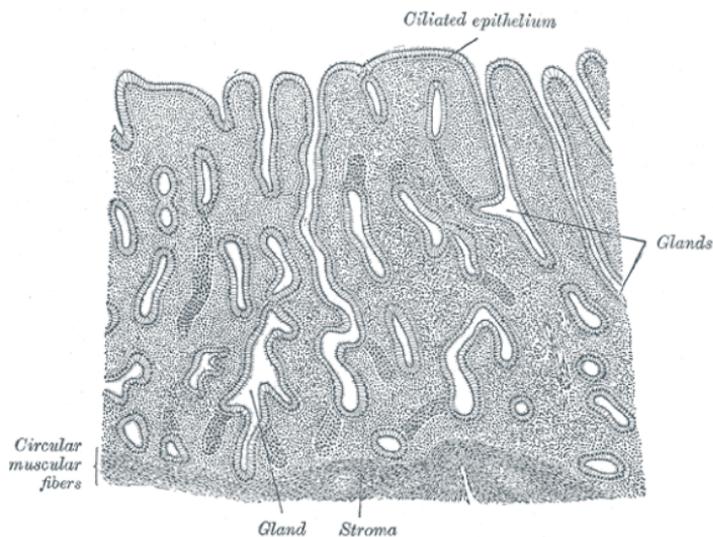


Figure 1 Normal endometrium is less than 5 mm thick.

Luteal phase

The second part of the menstrual cycle is the two weeks from the time you release an egg until menstruation begins, called the luteal phase. It gets its name from the **corpus luteum** (yellow body) in the ovary, which is the empty yellow socket (follicle) from which the egg was released. The corpus luteum releases the hormone progesterone during the luteal phase to further prepare the endometrium for receiving the fertilized egg. This secretory endometrium becomes thicker, more nutritious and develops a better blood supply to nurture the fertilized egg. The luteal phase last for at least 12 days. If your luteal phase lasts for less than 10 days, then you have a **short luteal phase** and your estrogen levels are most likely not balanced by a sufficient amount of progesterone.

Withdrawal bleeding

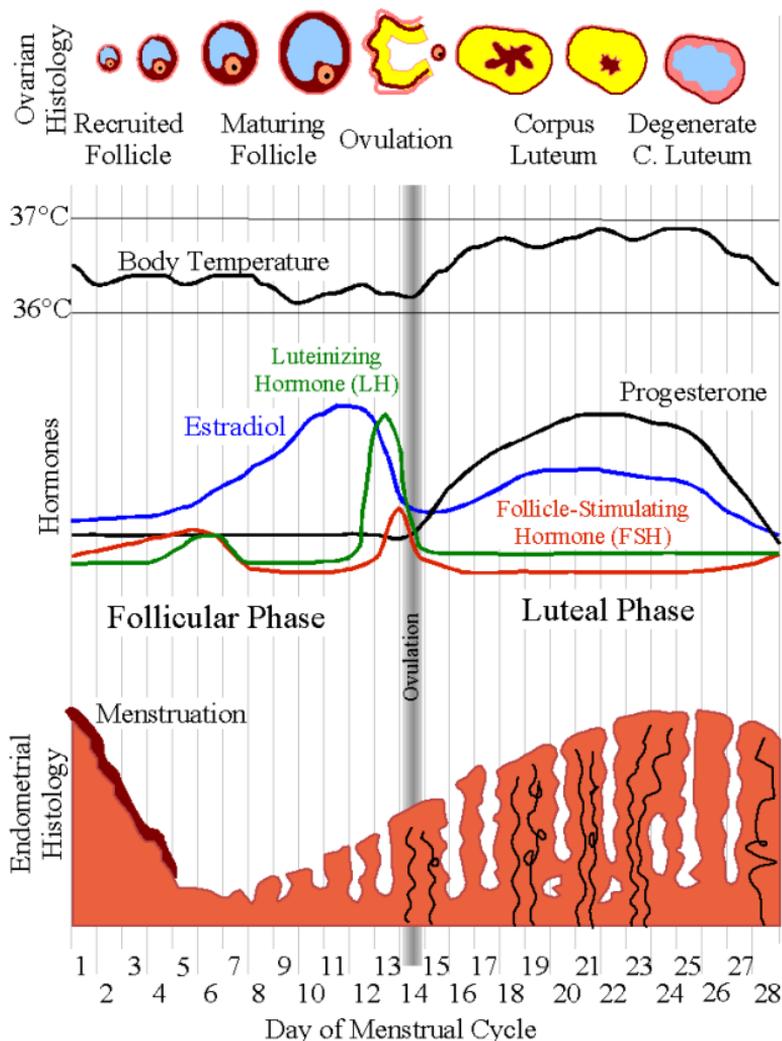
The third part of the menstrual cycle is withdrawal bleeding or period. This happens only if no fertilization takes place. Most women have one menstrual cycle every 22-35 days, most commonly 28 days.

A few women have a regular cycle of 18-40 days, and if that is consistent, fairly painless, and not excessively heavy or light, then it is considered a normal variation.

Calculate Day 1 of your cycle as the first day you start bleeding. Day 1 should be the day when the heaviest bleeding occurs. Bleeding should last only 3-5 days. Normal blood loss is 10-35 ml, or 2-7 soaked sanitary pads per cycle. The absolute maximum blood loss during a heavy cycle should be 45-60 ml per cycle. If it exceeds this amount, the woman is at risk of developing iron deficiency anemia. If you soak 16 pads or more per cycle, then you have **menorrhagia** and are at risk of developing iron deficiency anemia. Normal menstrual blood is dark or brownish, not bright red.

Normal menstrual blood does not clot easily because it:

- is high in calcium
- lacks the clotter prothrombin
- has very low levels of the clotter fibrinogen



(Average values. Durations and values may differ between different females or different cycles.)

Figure 2 Female Menstrual Cycle 2 by Lyrl, May 20, 2007.

In order for a woman to ovulate, she requires these hormones in perfect balance:

1. Gonadotropin-releasing hormone (GnRH) from the hypothalamus in the brain
2. Follicle stimulating hormone (FSH) from the pituitary gland in the brain to stimulate egg growth in the ovary
3. Thyroid stimulating hormone (TSH) from the pituitary gland to stimulate the thyroid gland in the neck
4. T3 and T4 from the thyroid gland to stimulate metabolism and allow ovulation
5. Luteinizing hormone (LH) from the pituitary gland to release the egg from the follicle in the ovary
6. Estrogen from the ovary to stimulate the lining of the uterus to grow (follicular phase)
7. Progesterone from the corpus luteum (yellow body on the ovary from which the egg burst) to mature the uterine lining to be nutritious for the fertilized egg and support a pregnancy. Progesterone levels drop and causes the endometrial lining to shed in a menstrual period if the egg is unfertilized

This combination and timeframe is represented by the graphic below.

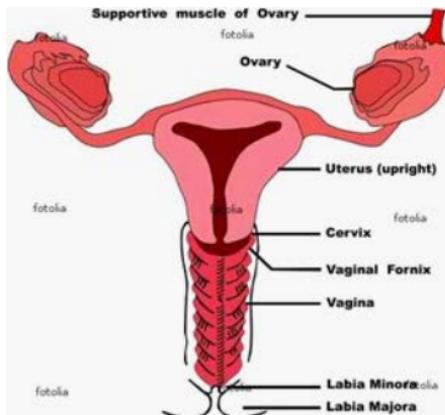


Figure 3 Female reproductive system.

How can I detect ovulation?

If you have variable periods, counting days is ineffective for determining when you ovulate. Look for these signs of ovulation:

- Your cervical mucus looks like egg white (clear, slippery, and stringy)
- Your basal body temperature (BBT) before you arise from bed is elevated 0.2°C (0.4°F-0.6°F) above its usual level (around 37°C)
- Slight to mild pelvic pain
- Possible spotting or slight bleeding for 1-2 days mid-cycle (not equivalent to a menstrual flow)

You can also use an ovulation test kit, available from your pharmacist. Prices vary from about \$20-\$65.

If you do not have these signs and symptoms of ovulation mid-cycle, then the following menstrual period will possibly be heavy and/or painful due to anovulation

How do I calculate blood loss?

A regular menstrual pad or tampon holds around 5 milliliters (ml) of blood. To calculate the approximate amount of blood you have lost if you wear regular pads or tampons, multiply the number you used by the number of days you have been bleeding. For example:

10 regular pads X 5 days = 50 ml of blood lost (a heavy period)

An overnight pad or super tampon holds around 10 ml of blood. To calculate the approximate amount of blood you have lost if you wear extra-absorbent pads or tampons, multiply the number you used by the number of days you have been bleeding. For example:

20 extra-absorbent pads X 10 days = 200 ml (menorrhagia)

In the first example, you do not require treatment. In the second example, you require treatment to prevent iron deficiency anemia.

If you are really concerned about being absolutely accurate, you can:

1. Weigh a dry pad and record the result
2. Weigh each and every pad you use during the entire period and record the results

However, this type of exact measurement is time-consuming and usually unnecessary. If you think you have **menorrhagia**, your doctor will verify your estimate with a Complete Blood Count (CBC) and iron studies. The doctor will pay particular attention to the **hemoglobin** and **hematocrit** results included in the CBC, and the **ferritin** level in the iron studies. Low levels of hemoglobin, hematocrit and ferritin confirm that you have anemia.

What causes anovulation?

Anovulation can occur for a variety of reasons. Traumatic events such as high or prolonged stress, grief and extreme physical exertion can be disruptive to the normal ovulatory cycle. More commonly anovulation is the result of exposure to estrogens either natural, supplemented or environmental. Anovulatory cycles is one of the potential consequences of what is commonly termed **estrogen dominance** and is characterized by high surges of **estrogen** and low levels of **progesterone**. Full details about estrogen dominance can found by downloading the booklet Understanding Estrogen Dominance at www.understandingestrogendominance.com.

Taking an oral contraceptive is a chemically induced form of anovulation. Birth control pills suppress the release of an egg and thus prevents pregnancy. Many women do not realize that this suppression of ovulation is how the Pill actually works and in doing so results in little or no natural progesterone production.

Anovulation is a normal consequence of frequent breastfeeding. However, it is not always the case and you may still release an egg if you do not breastfeed every two hours, so use contraception if you do not want your children spaced closely together.

Anovulation can also be caused by the following:

- The onset of menopause (**perimenopause**)
- Depleted egg supply
- Eating disorders (obesity, anorexia, or malnutrition)
- Genetic disorders
- Heavy athletic training
- High and/or sustained stress

- Occupational exposure to radiation or environmental toxins
- Pituitary gland tumor in the brain
- [Polycystic ovarian syndrome \(PCOS\)](#)
- Smoking, alcohol and/or drug abuse

Why is anovulation a problem?

Anovulation is a significant health issue and should not be ignored. Anovulation results in a serious hormonal imbalance between estrogen and progesterone and is often overlooked as the cause of many seemingly unrelated symptoms.

In women the overall symptoms as a result of a failure to ovulate are often nondescript and include:

- a general malaise
- a feeling that something is just not right
- of not being on top of life and
- a general loss of confidence in one's self and abilities.

Physically, mentally and emotionally the most common symptoms include:

- mood changes
- forgetfulness/memory blanks
- tiredness/fatigue
- irritability/anxiety/anger
- sleep disturbances
- decreased concentration
- breast tenderness/soreness
- aches and pains
- fluid retention/bloating
- sugar cravings
- menstrual changes
- increased body fat/weight gain
- lowered sexual desire

An evaluation of the severity of the symptoms of progesterone deficiency due to anovulation can be made by taking the [Progesterone Deficiency Self Assessment online quiz](http://www.profeme.com) at www.profeme.com.

Symptoms	None	Mild	Moderate	Severe
Water Retention/bloating/weight gain	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Increased facial hair	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Breast tenderness/swelling	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Pain: Headache/migraine/low back/muscle ache/joint ache	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Vaginal dryness/pain/itching	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Fatigue/lack of energy	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Decreased concentration/alertness /memory loss	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
Urinary Incontinence	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>

Figure 4 Progesterone Deficiency Quiz

Ovulatory changes with age

Puberty (approximate age 11-15 years)

Puberty is the change from childhood to sexual maturity. In 1850, most girls experienced puberty around 17. In 1950, most girls experienced puberty around 13. Today, girls as young as 6 years old are developing breasts, and frequently some begin menstruating by the ages of 8-11.

Puberty begins when the hypothalamus in the brain releases gonadotropin-releasing hormone (GnRH) to tell the pituitary gland to release gonadotrophins. The gonadotrophins (luteinizing-hormone(LH) and Follicle-Stimulating Hormone (FSH) wake up the ovaries, which in turn produce the hormone estradiol which stimulates the growth of breast tissue and maturation of the reproductive organs. The adrenal glands then produce androgens to start the growth of pubic hair. Menstruation follows about one to three years later, when estrogen and progesterone start cycling on and off monthly. Often it can take 3-5 years before pubescent girls menstrual cycles settle into a regular and predictable pattern.



Young Adulthood (15 – 35 years)

Ovulatory disturbances in this phase of a woman's reproductive life result in diminished production of progesterone.

The most common effect is [premenstrual syndrome \(PMS\)](#), also called premenstrual tension or PMT) a week or two before your period. About 85% of women experience at least one of these signs and symptoms of PMS during their reproductive life:

- Acne
- Swollen, tender breasts
- Fatigue
- Sleep disturbance
- Digestive troubles, like diarrhea, constipation, bloated abdomen, food cravings, or indigestion
- Headache
- Backache
- Mood swings and crying spells
- Psychological problems, like depression, trouble remembering, inability to concentrate, irritability, anxiety, or feeling tense

Symptoms abate after bleeding starts. PMS is best addressed by the use of progesterone ([ProFeme® 3.2%](#)) cream from day 12-26 of the cycle. Left untreated, PMS can develop into a more serious disorder, called [Premenstrual Dysphoric Disorder \(PMDD\)](#).

About 10% of young women develop [endometriosis](#) (endo), a hormonal imbalance and immune dysfunction where the lining of the uterus (endometrium) grows outside the uterus. Endometrial tissue can travel to the bladder, bowel, lungs or other organs, and sheds during menstruation. The initial symptoms are similar to PMS, but get worse over time. Suspect endometriosis if you have pain after sex, or with bowel movements or urination during your period.

If untreated, severe endometriosis can lead to infertility due to scar tissue. Endometriosis is closely linked to a failure to ovulate and an under production of progesterone.

You are more likely to develop endometriosis if:

- You had an early puberty
- A close relative has it (mother, sister or aunt)
- You have heavy periods lasting more than 7 days
- Have a short cycle of 27 days or less

Depending upon the severity of the endometriosis treatment options can vary. Initial management of endometriosis is best addressed by the use of progesterone (**ProFeme® 3.2%** or **ProFeme® 10%**) cream from day 12-26 of the cycle. For detailed information on endometriosis management options see www.understandingendometriosis.com

Young women may also develop **Polycystic Ovary Syndrome (PCOS)**, which occurs when the woman produces:

- Low levels of follicle stimulating hormone (FSH), so her eggs are underdeveloped and she fails to ovulate, and
- Constantly high levels of luteinizing hormone (LH), instead of a mid-cycle surge of LH, and
- High levels of male androgens, often resulting in obesity, abnormal male-pattern hair growth (hirsutism) and acne

The eggs cannot burst free from the ovary in women with PCOS. Instead, they form painful, liquid-filled sacs called cysts. A woman with PCOS may ovulate intermittently or not at all. She may menstruate unpredictably or not at all. She is **estrogen dominant** due to an overall progesterone deficiency due to the failure to ovulate. PCOS is best addressed by the use of progesterone (**ProFeme® 3.2%**) cream from day 12-26 of the cycle. For detailed information on PCOS see www.undertandingpcos.com

Perimenopause (mid 30's onwards)

Perimenopause is the slowing down of your reproductive hormones, estrogen, progesterone, and testosterone from age 35 onwards. Your ability to become pregnant decreases. You may skip menstrual periods. Your flow changes and may become either heavier or lighter. If your periods were very regular, they may become irregular. Remember that even though you ovulate erratically during perimenopause, you still can become pregnant. Contraceptive measures need to be used

because your fertility is unpredictable during this time. Often the use of estrogen-based oral contraceptives (the Pill) will exacerbate perimenopausal symptoms due to [estrogen dominance](#). See www.understandingestrogendominance.com.

Your interest in sex may diminish – [low libido](#). You may develop [night sweats](#). You may experience a lack of concentration and poor short term memory. Your waist thickens. You could leak urine or have more bladder infections. If the diaphragm was your birth control method of choice, its rim may now aggravate your bladder. Your vagina may feel dry, so sex can be painful ([dyspareunia](#)). The discomfort of perimenopause can last for years. Perimenopausal symptoms are due mostly to declined progesterone levels due to diminished or an absence of ovulation. Most perimenopausal symptoms are best addressed by the use of progesterone ([ProFeme® 3.2%](#)) cream from day 12-26 of the cycle if the cycle is still regular or for 3 weeks in every four if irregular. [ProFeme® 10%](#) cream may be required if menstrual bleeding is very heavy. For detailed information on the management of perimenopausal symptoms see www.understandingperimenopause.com

Menopause

Menopause marks the end of childbearing. It occurs when ovulation and menstrual periods cease for at least 12 months and the woman becomes permanently infertile. Most women experience menopause at age 45-55. Postmenopausal bleeding is a very serious symptom that may be associated with cancer of the uterus. See your doctor if you experience [uterine bleeding](#) after the change of life.

Menopause is a time in a woman's life of great changes both physically and emotionally. For detailed information on the menopause transition see www.understandingmenopause.biz

More serious medical conditions.

A failure to ovulate consistently in a regular menstrual pattern is an indication that there is a hormonal imbalance which may or may not lead to a more severe medical condition. The following conditions are a

possible consequence of consistent failure to ovulate which results in an overall progesterone deficiency.

Anemia

Anemia means lack of red blood cells. If you bleed very heavily during menstruation, you can develop iron deficiency anemia, and in extreme cases, low blood volume. If you become anemic, you will feel tired and withdrawn. You will look pale. If you have dark skin, your mucous membranes will look pale. You may stop menstruating or have prolonged, **heavy bleeding**. A Complete Blood Count (CBC) and ferritin blood level will confirm if you have anemia. Immediate treatment is iron supplementation and the use of progesterone (**ProFeme® 3.2%**) cream from day 12-26 of the cycle will address the underlying progesterone deficiency causing the heavy bleeding and anemia.

Menorrhagia

Menorrhagia is heavy bleeding more than 80 ml per cycle, or 16 soaked sanitary pads per cycle. Women generally notice a gradual increase of menstrual flow over many months before seeking treatment. **A sudden onset, painful or heavy unexplained menstrual blood loss needs to be investigated by a doctor immediately because it is unlikely to be menorrhagia.** Menorrhagia is serious because it eventually leads to iron deficiency anemia. Most of the time, menorrhagia occurs because of an imbalance in estrogen and progesterone hormones or from benign (non-cancerous) uterine tumors called **fibroids**. Women with menorrhagia notice a slow and steady increase in blood volumes over many months. Very rarely menorrhagia is caused by a genetic bleeding disorder, like von Willebrand's disease. Heavy periods and menorrhagia is best addressed by the the use of progesterone (**ProFeme® 3.2% or 10%**) cream from day 12-26 of the cycle for three cycles to alleviate heavy menstrual flow. For detailed information see www.understandingheavyperiods.com or www.understandingmenorrhagia.com



Metrorrhagia

Metrorrhagia is irregular uterine bleeding between expected menstrual periods. Women with metrorrhagia are prone to anemia from excessive blood loss.

Causes of metrorrhagia generally include:

- Hormonal imbalance due to insufficient progesterone production
- **Fibroid** tumors in the uterus
- **Endometriosis** (the womb's lining grows outside the uterus)

Metrorrhagia is best addressed by the the use of progesterone (**ProFeme® 3.2%**) cream from day 12-26 of the cycle.

Menometrorrhagia

Menometrorrhagia is irregular **and** heavy uterine bleeding. The woman with menometrorrhagia bleeds during her expected menstrual period and also at irregular intervals. She is very likely to develop iron deficiency anemia.

Menometrorrhagia is best addressed by the the use of progesterone (**ProFeme® 3.2%**) cream from day 12-26 of the cycle.

Endometrial Hyperplasia

Endometrial hyperplasia occurs when the endometrial cells lining the uterus grow too quickly (proliferate), usually because the woman produces normal or high levels of the hormone estrogen and not enough progesterone.

The glands in the endometrial lining develop irregular shapes and varying sizes, which predisposes the woman to developing cancer later. The uterus enlarges to the size of a three-month pregnancy and the lining is very thick. (Normal lining is 5 mm or less in thickness; hyperplasia is often over 20 mm.) The woman usually has irregular, heavy bleeding (menometrorrhagia) with anemia and pain. As the uterus continues to enlarge, it pushes on the bladder and rectum, so the woman may develop frequent urination and constipation. Hyperplasia can be a symptom of:

- **Polycystic ovary syndrome (PCOS)**
- **Anovulatory cycles**
- **Submucosal fibroids**

- Perimenopause
- Pelvic radiation
- Tamoxifen to prevent breast cancer
- Exogenous estrogen therapy
- Obesity
- Postmenopausal bleeding due to cancer

TYPES OF HYPERPLASIA	CHANCE OF DEVELOPING CANCER
Simple	1%
Complex	3%–5%
Simple with atypia	8%–10%
Complex with atypia	25%–30%

Simple and complex hyperplasia regresses spontaneously in 80% of cases without atypia (the precursor of cancer), however the situation needs to be monitored by your doctor.

If you decide on treatment for **endometrial hyperplasia**, then your gynecologist will biopsy your endometrium by scraping it with a Pipelle (a flexible suction curette). The biopsy can be performed in the doctor's office or in a hospital as part of a D&C. Your gynecologist may also order an ultrasound or hysteroscopy to confirm the findings. The pathologist at the laboratory will look for abnormal cells that indicate a precancerous condition, called atypia.

For simple and complex hyperplasia's a gynecologist may prescribe progesterone (**ProFeme® 3.2% or 10%**) cream or synthetic progestin to prevent endometrial hyperplasia from developing into atypia.



Progesterone therapy lasts for six months. You will be recalled for a second biopsy. If the lining of your uterus is normal and your symptoms have disappeared, then progesterone therapy ends or a low maintenance dose

continued. If the lining of your uterus is still abnormally thickened and your symptoms have continued, then more severe therapies may be employed. For detailed information on endometrial hyperplasia and treatment options see www.understandingendometrialhyperplasia.com.

PMS – Premenstrual Syndrome

Take a multivitamin supplement containing 400 micrograms of folic acid and 1,000 milligrams of calcium. Take ibuprofen starting the week before your period begins. Avoid smoking and bingeing on salty or sugary foods, alcohol, or caffeine. Try to get eight hours of sleep nightly. If symptoms persist supplementing progesterone to address the progesterone deficiency usually resolves symptoms within three cycles - use [PRO-FEME® 3.2% cream](#). For detailed information see www.understandingpremenstrualsyndrome.com

What is the role of progesterone in humans?

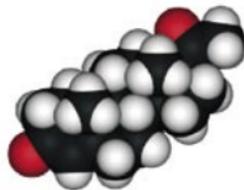
Progesterone is the hormone that regulates menstruation, supports pregnancy, tempers the highly stimulatory effects of estrogen and helps an embryo develop by providing a source of corticosteroids. Natural progesterone is a steroid hormone derived from cholesterol and is vital as a precursor hormone in the body's production of corticosteroids and glucocorticoids – steroids that help us deal with stress and physical cellular/tissue repair. Progesterone is normally produced by the corpus luteum in the ovaries and in the brains of humans and animals. At about 8 to 10 weeks of pregnancy, the placenta in pregnant females takes over progesterone production from the ovaries. Progesterone is the pivotal hormone of [pregnancy](#). Women in their childbearing years experience cyclical progesterone surges. In the beginning (follicular phase) of a menstrual cycle, women have low progesterone levels equivalent to that in men, children, and post menopausal women (less than 2 ng/ml of blood). The small amount of progesterone present in males does not have a feminizing effect on them. Progesterone calms mood in both sexes. When a woman releases an egg for fertilization (ovulation), her progesterone level spikes (greater than 5 ng/ml of blood). If the egg (ovum) is fertilized, the corpus luteum (yellow body) in the ovary secretes

progesterone to maintain the pregnancy until the placenta is large enough to take over production. Progesterone levels increase to 400 ng/ml of blood, and taper off during the last month of pregnancy to 200 ng/ml. After birth occurs and milk production (lactation) begins, women experience “baby blues” because the progesterone levels decrease abruptly.

Progesterone is a neurosteroid in the brain that affects functioning of the nerve synapses and the protective myelin sheath of nerves. Researchers are investigating the effects of progesterone on memory, cognition, and multiple sclerosis. Animal studies suggest progesterone may protect females from brain injury.

Progesterone reduces spasms in smooth muscles. It is an anti-inflammatory and decreases immune response. Progesterone adjusts the body’s use of zinc, copper, fat, estrogen, collagen, and blood clotting factors. It is a hormone that influences the function of the uterus, gall bladder, thyroid, bones, teeth, skin, ligaments, tendons, and joints.

Women use progesterone to prevent **excessive menstrual bleeding** and to assist with in-vitro fertilization. A woman who is prone to **miscarriage (especially repeat first-term miscarriages)** can use progesterone to help maintain her pregnancies, because it reduces pre-term births and the time babies spend in neonatal intensive care units.



Progesterone molecule

Mood changes, anxiety, depression, weight gain, irregular periods, headache, migraine, infertility, miscarriage, premenstrual syndrome (PMS), post partum depression, endometriosis, pregnancy problems, breast disorders and polycystic ovarian syndrome (PCOS) are some of the medical conditions associated with reduced progesterone production.

Are there side-effects associated with using natural progesterone?

PROFEME® natural progesterone cream has very low toxicity. The most common problems associated with progesterone treatments are that they can cause symptoms similar to the feeling of pregnancy:

- Tender breasts
- Fatigue

- Mood swings
- Constipation or diarrhoea
- Headache
- Muscle or joint pain
- Occasionally breakthrough bleeding (spotting)
- Fluid retention
- Dizziness

If these occur, a simple adjustment of dose usually resolves the problem. Side-effects, if they occur, are usually experienced at the onset of treatment and are considered a positive sign. Side-effects usually resolve themselves fully within 10 days of a dose reduction and often sooner.

What about homeopathic and herbal treatments?

Homeopathy is a complementary therapy. Homeopaths claim that like cures like. Essentially, homeopaths believe that if a substance causes a disease, then you can cure it by taking a very minute, diluted amount of the same substance.

Homeopathic treatments contain NO progesterone or testosterone, nor have they been demonstrated to cause any change in testosterone or progesterone levels.

The herb Chaste berry (*Vitex agnus castus*) does not contain progesterone, but it may indirectly help you produce progesterone over the course of several months by stimulating your pituitary gland to produce luteinizing hormone. Chaste berry has unpleasant side effects, such as an itchy skin rash, nausea, dry mouth, digestive upset, hair loss, headaches, rapid heartbeat, and bleeding between periods. *Vitex* is called chaste berry and monk's pepper because it was used for centuries to reduce libido. Do not use chaste berry if you are pregnant, breastfeeding, or have endometriosis, fibroids, cancer of the ovaries or breast, schizophrenia, or Parkinson's disease. It is unsafe to take chaste berry in conjunction with these prescription drugs: Bromocriptine; cabergoline; carbidopa-levodopa; chlorpromazine; Clozaril®; Haldol®; Mirapex®; oral contraceptives; Reglan®; Requip®; Risperdal®; Seroquel®; thioridazine; trifluoperazine; and Zyprexa®. Inform your doctor and pharmacist that you are taking chaste berry before starting any new medication to avoid adverse drug interactions.

The herbs tribulus, horny goat weed, Tongkat Ali Extract (*Eurycoma longifolia*) and *Mucuna Pruriens* Extract have not been shown in scientific testing to increase blood testosterone levels despite extravagant marketing claims. To avoid adverse drug interactions inform your doctor and pharmacist before taking any of these or other pharmaceutical or herbal preparations.

Wild yam treatments sold in health food stores contain a steroid substrate called diosgenin, which is chemically similar to progesterone, but does not act like progesterone within the body. Humans cannot convert diosgenin into progesterone – a point often misrepresented by marketers of wild yam products. Wild yam treatments are *totally ineffective* as a progesterone supplement or for treating [estrogen dominance](#) symptoms.

How do I use PROFEME® progesterone cream?

The aim of treatment with PROFEME® progesterone cream is to mimic the body's normal natural hormone production as much as possible. PROFEME® dose applicators are marked in 0.5ml doses. You must tailor the strength, amount and the number of days you apply the cream to your individual requirements. Your doctor or health care professional may alter the dose recommended in this booklet.

Women's hormonal cycles are more complex than the hormone profile of men.

PROFEME® 3.2% progesterone cream is used to control the symptoms of [benign breast disorders](#) during [premenstrual syndrome \(PMS\)](#), [menopause](#), and [peri-menopausal symptoms](#). PROFEME® treats other progesterone-deficiency conditions, such as surgical menopause from [hysterectomy](#), [ovarian cysts](#), [uterine fibroids](#) and [fibrocystic breasts](#). If you have had a hysterectomy, the doctor may prescribe estrogen-only for menopausal symptoms to manage [hot flashes](#) and [night sweats](#). In hysterectomized women it is very important that unopposed estrogen must be supported with natural progesterone to prevent symptoms of [estrogen dominance](#).

PROFEME® progesterone cream is supplied in two strengths – 3.2% and 10% w/v containing 32mg progesterone per ml and 100mg progesterone per ml. Each tube is supplied with a graduated dose measuring applicator.



Recommended starting doses for using PROFEME® natural progesterone cream are as follows:

- **Peri-menopausal women.** Apply 1ml of PROFEME® 3.2% cream via measured applicator (32mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. If a menstrual period starts prior to day 26 cease using PROFEME® and consider the first day of bleeding as Day 1 of the new cycle. This is a common occurrence when initiating treatment in peri-menopausal women and should be considered a sign that the treatment is having a positive effect. Symptoms abate in 2nd or 3rd month of use.
- **Premenstrual syndrome (PMS).** Apply 1ml of PROFEME® 3.2% cream via measured applicator (32mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. Significant alterations to this dosage may be made to achieve a crescendo effect 4-5 days prior to menses. Symptoms abate in 2nd or 3rd month of use.
- **Premenstrual dysphoric disorder (PMDD).** Apply 0.5 - 1ml of PROFEME® 10% cream via measured applicator (50-100mg progesterone) daily or in divided doses from day 12-26 of each menstrual cycle. Significant alterations to this dosage may be made to achieve a crescendo effect 4-5 days prior to menses. Symptoms abate in 2nd or 3rd month of use.
- **Endometriosis and Postpartum depression.** Apply 1.0 - 2.0ml of PROFEME® 10% cream via measured applicator (100-200mg progesterone) daily or in divided doses depending upon the severity

of the condition. In reproductive cyclical women initiate treatment on a day 12-26 basis, but this may need to be increased to three weeks use in every four if symptoms/pain emerge upon withdrawal.

- **Infertility/Repeated First-term.** Miscarriage Luteal phase and first trimester corpus luteal support. Apply 1ml of PROFEME® 10% cream (100mg progesterone) daily or in divided doses via measured applicator from day 12-26 of each cycle until pregnancy is confirmed and then 1-2ml daily on a continuous basis until at least week 13 or until full term.

Before conceiving, a woman prone to miscarriage should use PROFEME® 3.2% cream from days 12 to 26 of the cycle until the pregnancy is confirmed. If spotting occurs at week 6 or 7 of pregnancy, a high dose of 100 to 200 mg progesterone cream (PROFEME® 10%) twice or three times daily. Often, women use PROFEME® natural progesterone cream until the baby is full term (40 weeks of gestation).

Note: Amount and duration of application for all conditions must be tailored to individual requirements

PROFEME® 3.2 and PROFEME® 10 Prescribing Information and Consumer Medicine Information can be downloaded from <http://www.profeme.com> or clicking on these images below.



PROFEME® 3.2% CMI



PROFEME® 3.2% PI



PROFEME® 10% CMI



PROFEME® 10% PI

Why is ProFeme® progesterone cream the best?

If one Googles “natural hormone cream” , “progesterone cream” or “testosterone cream” there are dozens of products claiming to be the “best” and “authentic” natural progesterone/testosterone creams or gels. Just how does one determine which product is most suited to his/her requirements? The following is an outline of basic manufacturing processes to help you decide. The three quality standards of natural progesterone cream are:

- 1. Pharmaceutical Grade:** The manufacturer operates to international standards of Good Manufacturing Practice (GMP). GMP means all production processes are standardized and controlled from the time the raw material is procured through to the expiry date printing on the finished product. The Australian government, like the U.S. and European regulators, enforces rigid government controls on the manufacturing facility, its equipment, processes, and packaging. PROFEME® natural progesterone creams are guaranteed stable, effective, and potent and the world’s only pharmaceutical grade progesterone cream. The final product has detailed documentation and is backed by clinical trials that substantiate its therapeutic claims.
- 2. Cosmetic Grade:** This is the quality sold over-the-counter in drug, department and grocery stores. Cosmetic grade products do not undergo the rigorous checking processes as is required of pharmaceuticals. Often, brand-names have exactly the same ingredients as generics, just with a different label. Cosmetic grade products are allowed a high bacterial content, so their shelf-life is very limited (usually 3 to 6 months). Cosmetic manufacturers are not required to register their products with the government regulators because cosmetic products do not require clinical trials to prove their worth. Cosmetic grade production is a self-regulating industry.
- 3. Compounded Product:** Natural health products from pharmacists, herbalists, homeopaths, naturopaths, and practitioners of traditional Indian and Chinese medicines are compounded. This means the product is tailored to the patient’s individual needs in the delivery system most desired. Pharmacists compound drugs that are not commercially available, or in a different strength than that readily

available. A compounded product may be needed to make a drug palatable. A compounded product may be needed if the patient reacts to dyes, preservatives, and allergens found in commercial products. Compounded products do not undergo any form of production control, concentration, impurity, stability or efficacy testing. Safe shelf-life is usually extremely short, if at all known. Compounded items are time-consuming to make, so generally they are more expensive.

About Lawley Pharmaceuticals

Lawley Pharmaceuticals (www.lawleypharm.com.au) is a privately owned pharmaceutical company which focuses on the transdermal administration of the naturally occurring hormones progesterone, testosterone and estradiol. Founded in 1995 by pharmacist Michael Buckley, Lawley Pharmaceuticals has grown to become a world leader in research and development of transdermal hormone preparations.

The only pharmaceutical grade natural hormone creams available worldwide are those made by Lawley Pharmaceuticals, Australia.

Lawley Pharmaceuticals (www.lawleypharm.com.au) makes PROFEME® 3.2% and 10% progesterone cream for females, ANDROFORTE® 2 and ANDROFORTE® 5 testosterone cream for males, ANDROFEME® 1% testosterone cream for women and NATRAGEN® estradiol cream for women.

PROFEME® progesterone creams are specifically targeted for use in women with declined or lowered serum progesterone levels due to genetic disorders, surgical or chemical interventions, under-production by the ovaries or ageing. Applied topically to the skin, PROFEME® Progesterone creams for women are the world's only clinically trialled and tested pharmaceutical grade progesterone creams using natural bio-identical progesterone. PROFEME® progesterone creams are listed with the Australian government (AUST L 95334 / L 70886).

ANDROFORTE® 2, ANDROFORTE® 5 and ANDROFEME® are testosterone creams specifically targeted for use in men and women with declined or lowered serum testosterone levels due to genetic disorders, neurological disorders, surgical or chemical interventions

or under-production by the testes or ovaries and/or adrenal glands. Applied topically to the skin, ANDROFORTE® 2, ANDROFORTE® 5 and ANDROFEME® are the world's only clinically trialled and tested pharmaceutical grade testosterone creams using natural bio-identical testosterone.

ANDROFORTE® 2, ANDROFORTE® 5 and ANDROFEME® testosterone creams are listed with the Australian government (AUST L 166239 / AUST L 166238 and AUST L 169317 respectively).

NATRAGEN® estradiol cream for women is specifically for conditions of estrogen deficiency conditions including short-term use for menopausal symptoms not responsive to PROFEME® such as hot flashes, night sweats, vaginal dryness and atrophy. (AUST L 169397)

The Lawley Pharmaceuticals portfolio of products includes

AndroFeme® 1% testosterone cream for women



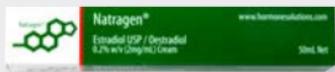
AndroForte® 2 and AndroForte® 5 testosterone creams for men



PRO-FEME® 3.2% and 10% progesterone creams for women



Natragen® 0.2% estradiol cream for women



Natural Progesterone for Women – Quick Q & A

- Q.** Is the progesterone in PROFEME® “natural” progesterone?
- A.** Yes. PROFEME® progesterone cream is guaranteed 100% to contain “natural” progesterone. Natural progesterone was the term coined by US doctor John Lee MD to differentiate between the chemical structure of progesterone produced by the ovaries (“natural”) and the chemical structures of the synthetically produced progestins which are often confused or misrepresented as being progesterone. Their chemical fingerprint is totally different and natural progesterone has a far greater diversity of action than progestins.
- Q.** Does the wild yam contain natural progesterone?
- A.** No - definitely not. The wild yam contains a steroid substrate called diosgenin that is similar in its chemical structure to progesterone. Diosgenin however does not act like progesterone within the body. The human body is unable to convert diosgenin into progesterone - a point often misrepresented by marketers of wild yam products.
- Q.** Where does “natural” progesterone come from?
- A.** Wild yam and soya are the two crops which contain steroid substrate (diosgenin and stigmasterol - plant hormones) similar in their chemical structure to progesterone. Because these two crops are grown in commercial quantities, large amounts of raw substrate material can be extracted. Diosgenin and stigmasterol are converted in a laboratory to make “natural” progesterone. This is the same chemical structure as produced by the ovaries and is identical in every way.
- Q.** Is the progesterone in PROFEME® progesterone cream made from genetically modified soya?
- A.** No - Lawley Pharmaceuticals in Australia, the manufacturers of PROFEME®, has documentation from the raw material manufacturers that the progesterone is not produced from genetically engineered soya crops.

- Q.** Why is PROFEME® progesterone cream superior to other progesterone cream brands?
- A.** PROFEME® progesterone cream is manufactured to pharmaceutical grade standards whereas in the USA and elsewhere, over-the-counter progesterone creams are made to cosmetic grade standards. The requirement for labeling disclosure of the amount of progesterone in the finished product is optional. Many products available in the USA for example may claim to have progesterone in the finished product, but in fact can have little or no progesterone. Because PROFEME® has much stricter standards of manufacture the amount stated on the label is guaranteed to be what is in the finished product. Additionally, PROFEME® progesterone cream has undergone comprehensive raw material purity testing, clinical trials and stability testing. The quality difference between PROFEME® Progesterone Cream and other cosmetic brands is significant.
- Q.** How long before PROFEME® progesterone cream helps my PMS or menopausal symptoms?
- A.** Usually it takes between 4 and 8 weeks for PROFEME® to significantly improve symptoms. Many people want an overnight cure to their menopausal problems or PMS symptoms. It must be remembered that the underlying hormone imbalance that leads to the point where symptoms warranted treatment usually developed over many months, if not years. They cannot be reversed overnight. Most people find that symptoms improve steadily with each month of use. After about 12 months use, maximum effect is achieved.

Our Mission Statement

Lawley Pharmaceuticals provides optimal delivery systems for the administration of naturally occurring hormones to counter endocrine deficiency states.

Our philosophy centres on the principle to replace “like with like”, to use a bio-identical hormone in preference to a synthetic hormone analogue when a viable clinical option and to advance areas of clinical research that has had little or no investigation using naturally occurring hormones.

Our goal is to establish, through evidence based medical research, bio-identical hormones as cornerstone treatments for diseases such as breast disease, infertility, male hypogonadism, female androgen deficiency, post partum depression and endometriosis.

Lawley Pharmaceuticals has established strong links with centres of medical excellence around the world and continues to push the boundaries of medical research.

Completed Clinical Studies

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3. Plasma and saliva concentrations of progesterone in pre- and postmenopausal women after topical application of progesterone cream. *O'Leary PJ et al. Presented at the Annual Congress of the Australian Menopause Society held in Perth, Australia in October 1997*
4. Long-term pharmacokinetics and clinical efficacy of AndroForte® 5 cream for androgen replacement in hypogonadal men. *Handelsman DJ et al. ANZAC Research Institute, Department of Andrology, Concord Hospital, Sydney, 2004.*
5. Transdermal testosterone therapy improves well-being, mood, and sexual function in premenopausal women. *Goldstat R et al. Menopause 2003; 10 (5): 390-398.*
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Internet Education Reference Sites

ANDROFORTE www.androforte.com

ANDROFEME www.androfeme.com

PROFEME www.profeme.com

NATRAGEN www.natragen.com

HORMONE SOLUTIONS www.hormonesolutions.com.au

HORMONESOLUTIONS www.hormonesolutions.com

ANDROPAUSE www.understandingandropause.com

ANOVULATION www.understandinganovulation.com

BREAST DISEASE www.understandingbenignbreastdisease.com

BREAST DISEASE www.understandingbreastdisease.com

BREAST DISEASE www.understandingbreastdisorders.com

CASTRATION www.understandingcastration.com

DUB www.understandingdub.com

DYSFUNCTIONAL UTERINE BLEEDING

www.understandingdysfunctionaluterinebleeding.com

DYSMENORRHEA www.understandingdysmenorrhea.com

DYSPAREUNIA www.understandingdyspareunia.com

EARLY MENOPAUSE www.understandingearlymenopause.com

ENDOMETRIAL HYPERPLASIA

www.understandingendometrialhyperplasia.com

ENDOMETRIOSIS www.understandingendometriosis.com

ESTROGEN DOMINANCE www.understandingestrogendominance.com

FEMALE SEXUAL DYSFUNCTION

www.understandingfemalesexualdysfunction.com

FIBROCYSTIC BREAST DISEASE

www.understandingfibrocysticbreastdisease.com

FSD www.understandingfsd.com

GYNECOMASTIA www.understandinggynecomastia.com

HEAVY PERIODS www.understandingheavyperiods.com

HORMONE MIGRAINE www.understandinghormonemigraine.com

HOT FLASHES www.understandinghotflashes.com

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OOPHORECTOMY www.understandingoophorectomy.com
OVARIAN CYSTS www.understandingovariancysts.com
PCOS www.understandingpcos.com
PERIMENOPAUSE www.understandingperimenopause.com
PMDD www.understandingpmdd.com
POLYCYSTIC OVARIAN SYNDROME
www.understandingpolycysticovariansyndrome.com
POSTNATAL DEPRESSION www.understandingpostnataldepression.com
POSTPARTUM DEPRESSION
www.understandingpostpartumdepression.com
PREGNANCY www.understandingpregnancy.biz
PREMENSTRUAL SYNDROME
www.understandingpremenstrualsyndrome.com
UTERINE FIBROIDS www.understandinguterinefibroids.com

References for Medical Professionals

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Glossary

You may hear these terms discussed in reference to yourself, your spouse, or your daughter:

Amenorrhea: The monthly menstrual cycle ceases due to one of these causes:

- Menopause
- Pregnancy
- Not eating enough (anorexia nervosa)
- Exercising too much
- Extreme stress

A serious underlying medical condition, such as uremia from end-stage renal disease (ESRD or kidney failure)

Anemia: Lack of blood. Women who bleed very heavily during menstruation develop iron deficiency anemia, and in extreme cases, low blood volume. Anemic women feel tired, and are withdrawn and pale. Dark skinned women have pale mucous membranes. Your family doctor orders a Complete Blood Count and ferritin levels to confirm that you have anemia, and will likely prescribe iron supplements until you can be seen by a gynecologist (doctor specializing in female organs).

BhCG: A pregnancy hormone excreted 10 days after conception, used to measure the age of the embryo. High levels can also mean cancer or multiple pregnancy. Low levels can mean death of the fetus, tubal (ectopic) pregnancy, or miscarriage.

D&C: Dilatation & Curettage, when the doctor scrapes the uterine lining to examine the cells for endometrial cancer, and to relieve the heavy buildup of the uterine lining (hyperplasia). D&C is also used for abortions early in pregnancy.

Dysmenorrhea: Painful menstruation. If it is caused by excessive prostaglandins, dysmenorrhea can usually be relieved with ibuprofen (Motrin), massage, heat packs, adequate rest, and mild aerobic exercise, like walking. If it is caused by hyperplasia, submucosal fibroids, or another uterine abnormality, the doctor must investigate further. Progesterone often relieves the pain associated with heavy menstruation from hyperplasia or fibroids.

Endometrial hyperplasia: Overgrowth of the womb's lining because of: Overstimulation by estrogen during perimenopause; estrogen-mimicking chemical toxins in the environment, such as pesticides on produce and phthalates in cosmetics and plastics; antibiotics and growth hormones in meat and milk; and obesity.

Fibroid tumors: Benign (non-cancerous) uterine tumors that can cause pain and heavy bleeding

FSH (follicular stimulating hormone): A hormone produced by the pituitary gland and the placenta, which stimulates the ovaries and controls reproduction.

Gonadotropin levels: The pituitary gland secretes a group of hormones called gonadotropins, which stimulate the testicles and ovaries.

Hypermenorrhea: Prolonged bleeding more than 7 days

Hypomenorrhea: Scanty menstruation

LH (luteinizing hormone): A gonadotropic hormone released by the pituitary gland in the brain, which stimulates females to ovulate

Menorrhagia: Heavy bleeding more than 80 ml per cycle, or 16 soaked sanitary pads per cycle, leading to iron deficiency anemia

Polymenorrhea: One menstrual period every 2-3 weeks; this is too frequent.

Prostaglandin: Chemicals that control the contractions of the uterus. Prostaglandin level is highest when your menstrual period begins. Too much prostaglandin contracts the uterine muscle so hard that the blood supply is cut off, the uterus is starved for oxygen, and pain results. Prostaglandins from the uterus can leak into the bloodstream and cause nausea, vomiting, diarrhea, and headache.

T3, T4, and TSH: A panel of blood tests used to evaluate the thyroid gland in the neck. Women with thyroid imbalance do not ovulate (release eggs for fertilization). A thyroid panel is standard for confirming that you are in menopause.

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