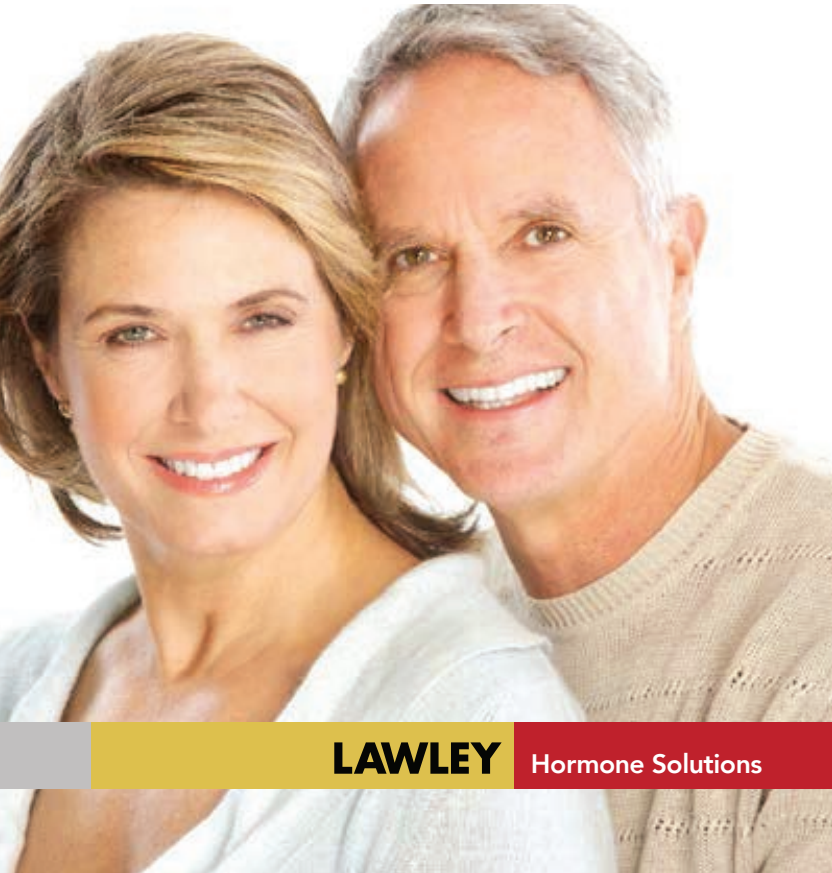
Understanding perimenopause in women



LAWLEY Hormone Solutions

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What is Perimenopause?

Perimenopause is the phase during which the female reproductive system winds down approaching menopause. ('Peri' means around and 'menopause' means cessation of monthly periods.) Perimenopausal ovaries no longer produce a predictable amount of the hormones progesterone, testosterone and estrogen. Perimenopause is an expected, natural part of ageing, not a disease. Some women have no or very mild perimenopausal symptoms. However, in many women ovarian insufficiency leads to:

- insomnia,
- fatigue,
- weight gain,
- forgetfulness,
- mood swings,
- menstrual problems and
- loss of sexual desire.

From the late thirties onwards, very subtle body changes take place triggered by gradual hormonal shifts. Women usually experience noticeable perimenopausal symptoms of varying intensity from the early forties until the onset of menopause. In about 20% of women acute symptoms affecting their quality-of-life may last for 3 to 6 years if steps are not taken to manage the symptoms. Perimenopausal symptoms are generally the result of estrogen dominance. Estrogen dominance is due to insufficient progesterone production from the ovaries to balance estrogen production. (for additional information, see www.understandingestrogendominance.com)

Menopause occurs the day after your final period finishes, so it is diagnosed in hindsight. It is the definitive end of menstruation and fertility, when no menstrual periods have occurred for 12 consecutive months. ('Mens' is Greek for month and 'pausis' means cease.) Menopause is also called the change of life or climacteric. Many people use the term 'menopause' to also cover perimenopause, when

symptoms of the change of life begin, but this is incorrect terminology.

What are the signs and symptoms of perimenopause?

In women the overall symptoms of estrogen dominance are often nondescript

- 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
    - irregular, prolonged and/or heavy flow
- increased body fat / weight gain
- lowered sexual desire

Some perimenopausal women may experience only one or two of these symptoms whereas others may experience many.

Key areas of health affected during perimenopause.

Fertility

During perimenopause, you may have difficulty falling pregnant, but you are not yet infertile. If you postponed pregnancy until your career was well established or for other reasons, you can still become pregnant, but may require assistance from a fertility expert. Irregular periods are a clue that you may be sub-fertile. No periods mean you are infertile.

Menstrual Irregularities

Perimenopausal menstrual changes can include skipped menstrual periods or periods can last significantly longer. Your flow can change, and generally become either heavier (menorrhagia) or irregular and infrequent (oligomenorrhea). Iron deficiency anemia from excessive blood loss causes chronic fatigue, withdrawal, cognitive problems and irritability. You may find you struggle at work or home because you have difficulty concentrating when your anemic blood cannot deliver sufficient oxygen to the brain and cells of the body.

One in every five hysterectomies is performed as a treatment for menorrhagia.

As the ovaries become less efficient, you may not produce an egg each and every month. Anovulatory cycles that do not produce an egg usually result in heavy periods, often with pain (dysmenorrhea). Your likelihood of having an anovulatory cycle is only 2% to 7% during your peak fertility (mid-20's to mid-30's), but jumps to 33% percent of cycles in women over 50.

Three of the most bothersome menstrual irregularities in perimenopausal women are:

1. **Menorrhagia**, which means heavy bleeding more than 80 ml per cycle, or 16 soaked sanitary pads per cycle. Menorrhagia is serious because it eventually leads to iron deficiency anemia. (for detailed information, see www.understandingmenorrhagia.com)

2. **Metrorrhagia**, which means irregular uterine bleeding between expected menstrual periods

3. **Menometrorrhagia**, which means heavy and irregular uterine bleeding. The woman with menometrorrhagia bleeds excessively during her expected menstrual period and also at irregular intervals, usually around two weeks apart, instead of the normal cycle of 28—35 days.

About 10% of all fertile women world-wide develop menorrhagia. In Australia, menorrhagia affects 5.1% of women and dysmenorrhea (painful periods) affects 29%. In the UK, 7 women in every 1,000 have menorrhagia. In the USA, 10 million women have menorrhagia.

Women with menorrhagia, metrorrhagia, or menometrorrhagia commonly develop anemia from excessive blood loss – iron tablets, injections or infusions are often required. An often recommended course of action by some doctors is hysterectomy (removal of the uterus). Generally, these collective problems occur due to **low progesterone production**.

They may also occur due to:

- Benign (non-cancerous) uterine tumors, called fibroids (see www.understandinguterinefibroids.com)
- Endometriosis (the womb's lining grows outside the uterus) (see www.understandingendometriosis.com)
- A gynecological cancer
- A genetic bleeding disorder, like von Willebrand's disease

For further information on menstrual irregularities see www.understandingdysfunctionaluterinebleeding.com

Sleep, Headaches and Cognition

You may develop night sweats and disturbed sleep from low progesterone and varying estrogen levels during perimenopause. Insomnia is common. You may not achieve deep slumber, and probably awaken feeling tired.

During the day, your fluctuating hormones may create hot flashes, depressive feelings and irritability. Low progesterone levels lead to lack of concentration, mood changes and poor short term memory.

Migraine headaches begin or worsen because hormones affect blood vessels in the head. Combined with your lack of restful sleep, these fluctuations can leave you tired to the point where your usual high performance degrades. Low progesterone and varying levels of estrogen is the underlying cause of most of these symptoms.

Tissue Changes

You could leak urine when you cough, sneeze or laugh. You may have more bladder infections as your urethra becomes less flexible and more easily damaged, due to hormonal deficiency. Your vagina is more prone to itchy yeast infections (candidiasis).

Your bones may thin out (osteoporosis). Consequently, your joints and back may ache.

You may feel a sensation like ants crawling over your skin, called **formication**. Your skin may thin, dry out, and become inelastic.

Your chances of developing heart and blood vessel diseases increase.

You will lose muscle mass and your fat distribution will concentrate in your abdomen. Expect your waist to thicken, whereas in your prime childbearing years your weight probably concentrated around your hips and thighs. Your metabolism slows, leading to weight gain, even though you stick to your usual diet.

Decreased sexual desire

Your interest in sex may diminish (low libido, lack of arousal, diminished desire, poor aoursal or absence of orgasm) and you may develop a dry vagina, so that intercourse is painful or irritating (dyspareunia). A less resilient vagina is more easily traumatized by penetrative sex. You may have difficulty achieving an orgasm. You may feel too tired for sex due to chronically disturbed sleep, lack of the hormone testosterone and iron deficiency due to menstrual irregularities.

When can I expect perimenopause?

You will probably have at least some perimenopausal symptoms starting a number of years before menopause. You will likely experience menopause around the same time your mother did, providing she had a natural menopause and not a hysterectomy. The world-wide age range for menopause is from the 30's to the 60's. Most Western women enter perimenopause around age 45, but it often occurs much earlier in Third World women. If you are Westernized and do not smoke, expect perimenopausal symptoms from age 45 until the average menopause at age 51. If you smoke, expect menopause to occur two years earlier, around age 49. Some women with **late menopause** experience perimenopausal symptoms at age 55 and menopause at 60.

If you had a simple hysterectomy, with only the uterus removed and the ovaries left intact, then you may experience menopause slightly earlier (around age 47), particularly if the surgeon has cut the nerves or blood vessels feeding your ovaries.

Premature menopause, primary ovarian insufficiency (POI) or early menopause is considered the end of childbearing ability before age 40. You may experience premature ovarian failure due to one of these conditions:

- Diabetes mellitus
- End-stage renal (kidney) failure (ESRD)
- Autoimmune disease (e.g., lupus)
- Thyroid disease
- Genetic abnormalities
- Cancer chemotherapy
- Radiation therapy
- Anorexia nervosa

For further information see www.understandingearlymenopause.com

Your doctor can measure your anti-Mullerian hormone (AMH) levels to predict the time when you will likely reach menopause, but the actual date will be influenced by other factors. If you smoke, have no children, take antidepressants, work with toxic chemicals, or received cancer treatment, then you are more likely to have an early menopause. If you have children or have been pregnant more than once, are overweight, or had high IQ test results as a child, then you are more likely to have a late menopause.

Generally speaking, measuring estrogen and progesterone hormone levels in a perimenopausal woman does not provide a clear picture of what is happening. During this time hormone levels swing wildly from day to day and month to month. A one-off blood or saliva hormone test is a waste of time and money, especially if taken outside the window of day 21-23 of the menstrual cycle when progesterone levels are peaking. Initially, evaluating symptoms is the best starting point for assessment followed by specific blood hormone and genetic testing depending upon the range and severity of symptoms. See Treatment Options.

How can I decrease my symptoms?

- Stop smoking, because it impairs the functioning of your ovaries.
- Keep a menstrual diary, including dates, flow, and moods, so you will know what worsens your symptoms. See the blank diary at the end of this booklet.
- If possible maintain a normal body weight via diet and exercise.
- If required, use a water-based lubricant for sex, never petroleum jelly.
- Avoid spicy food, hot beverages, and alcohol.
- Eat soy products and soy drinks.
- Avoid salt, sugar, and caffeine.
- Practice good sleep hygiene by going to bed at the same time every night, using cotton sheets with a high thread count, and keeping the bedroom dark and quiet.
- Exercise improves mood, keeps fatty deposits from settling around your waist, and strengthens your bones.
- Dress in layers, so if you feel hot, you can remove some clothing.
- Take a dietary supplement containing Vitamin D, calcium, and Vitamin E.
- Stay in air-conditioned areas.
- If the symptoms of low libido and fatigue persist after using bio-identical progesterone cream (PROFEME®) for longer than 3 months, have your free testosterone blood level taken by your doctor. Bio-identical testosterone (ANDROFEME®) may be required.

What are my treatment options?

Perimenopausal women can effectively control their symptoms using natural progesterone, testosterone and occasionally estrogen either alone or in combination depending upon individual circumstances.

The first step in managing perimenopausal symptoms is to clearly establish the underlying hormonal imbalance (usually estrogen dominance), or if you suffer from another condition with similar symptoms. An excellent starting point is to evaluate the severity of your symptoms. Taking a simple 15-item self-assessment questionnaire, Progesterone Deficiency Assessment Questionnaire, gives you an instant evaluation of the severity of your symptoms and also a baseline measurement by which to gauge your responsiveness to any treatment.

Symptoms	None	Mild	Moderate	Severe
Water Retention/bloating/weight gain	○	○	○	○
Increased facial hair	○	○	○	○
Breast tenderness/swelling	○	○	○	○
Pain: Headache/migraine/low back/muscle ache/joint ache	○	○	○	○
Vaginal dryness/pain/itching	○	○	○	○

An assessment score of 20 or greater generally indicates there is a progesterone deficiency with the higher the score the greater the deficiency.

An estrogen dominant perimenopausal woman will often experience a worsening of symptoms if given estrogen unless hot flashes & night sweats are present. Frequently, doctors will prescribe estrogens in the form of the Pill or HRT to perimenopausal women to stabilise and override ovarian function. More often than not a hysterectomy (removal of the uterus) is the frontline treatment offered to manage heavy periods!

In a reproductive woman blood testing of hormones is the most reliable of methods for hormone evaluation. There is a big push by some pathology labs and health practitioners to use salivary hormone assays claiming the results to be more reliable than blood testing. The problem is that salivary

hormones fluctuate wildly from hour to hour (particularly during the perimenopause) as the female reproductive system winds down. To get a true picture of what is happening with hormones when using salivary tests a great many tests need to be done over many days and even weeks which becomes extremely expensive.

Blood testing **at the correct time** of the menstrual cycle together with a full and thorough assessment of symptoms will tell more about progesterone deficiency than dozens of salivary hormone assessments. Timing is critical when testing hormones, because they are cyclical. **When testing progesterone levels in a cycling woman the ONLY time to test is between days 20-23 of the cycle**.

Ovulation takes place around day 13 of the cycle. Progesterone levels increase steadily and peak around day 21-22. Testing for progesterone during a period (days 1-5), just before ovulation (days 9-12) or just before menstruation (days 25-27) is a waste of time and money, similarly so is measuring hormone levels in a woman using The Pill. Many doctors fail to advise patients of this important information at the time of ordering hormone blood tests. If they did, they would see low progesterone blood results when levels should be high and realize that their patients were failing to ovulate and hence were progesterone deficient. Hormone levels, including testosterone, should always be measured in the morning when levels are highest.

Perimenopausal women with symptoms of estrogen dominance (normal or high estrogen and too little progesterone) will almost always benefit from PROFEME® progesterone cream.

PROFEME® safely and effectively reduces most perimenopausal symptoms by replacing the hormone of greatest deficiency and opposing estrogen dominance. PROFEME® achieves a steady state of hormone balance after 6—8 weeks of regular use (one or two cycles).

The recommended starting dose for treatment with PROFEME® progesterone cream in Perimenopausal women is:

- 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. Due to the many variations of perimenopausal symptoms, especially heavy and variable periods, the dose and frequency of PROFEME® application may need to be varied. To control heavy bleeding and regulate the frequency of periods PROFEME® 10% cream may be required at a dose of 0.5-1.5ml (50-150mg) daily for 3 weeks in every four until flow and frequency normalize, then use a lower dose from days 12-26. This may take 3-4 months to stabilize.

Women can also add testosterone to manage poor libido and unexplained fatigue if after 3 months progesterone has not resolved these symptoms. This is a common "off-label" practice among doctors in the USA and some parts of Europe, where regulators are yet to officially approve testosterone for use in women.

The situation is distinctly different in Australia.

ANDROFEME® 1% testosterone cream is tailored especially for women. Application of ANDROFEME® 1% testosterone cream involves no surgery, no pain or visible patches and is applied by the woman in the privacy of her own home. Importantly the dose is accurately controlled and adjustable. For detailed advice on the use of testosterone in women. See www.androfeme.com.

Very occasionally the perimenopausal woman may require estrogen supplementation if hot flashes, night sweats and vaginal dryness is a major problem. Natural estrogen (estradiol) in the form of a transdermal patch or gel is more beneficial than synthetic tablets of estrogen for short- term management of hot flashes and night sweats. If vaginal dryness is the only problem a natural estrogen (estradiol or estriol) vaginal cream or vaginal pessary inserted two or three times weekly will work safely and effectively without being absorbed systemically.

Some perimenopausal women have more advanced, specific or severe conditions which require specialized management which is not covered in depth by this booklet. For detailed information and treatment of:

- **Breast disorders** see www.understandingbreastdisorders.com
- **Early menopause** see www.understandingearlymenopause.com
- **Endometriosis** see www.understandingendometriosis.com
- **Endometrial hyperplasia** see www.understandingendometrialhyperplasia.com
- **Female sexual dysfunction** see www.understandingfemalesexualdysfunction.com
- **Fibrocystic Breast Disease** see www.understandingfibrocysticbreastdisease.com

- **Fibroids** see www.understandinguterinefibroids.com
- **Heavy periods** see www.understandingheavyperiods.com
- **Headache and Migraine** see www.understandinghormonemigraine.com
- **Hot flashes** see www.understandinghotflashes.com
- **Hysterectomy** see www.understandinghysterectomy.com
- **Infertility** see www.understandinginfertility.biz
- **Irregular Periods** see www.understandingirregularperiods.com
- **Low libido in women** see www.understandinglowlibido.com
- **Menopause** see www.understandingmenopause.info
- **Menorrhagia (heavy periods)** see www.understandingmenorrhagia.com
- **Miscarriage** see www.understandingmiscarriage.com
- **Mood changes** see www.understandingmoodchanges.com
- **Night sweats** see www.understandingnightsweats.com
- **Oophorectomy (removal of the ovaries)** see www.understandingoophorectomy.com
- **Perimenopause** see www.understandingperimenopause.com
- **Polycystic ovarian syndrome (PCOS)** see www.understandingpcos.com
- **Post partum depression** see www.understandingpostpartumdepression.com
- **Pregnancy** see www.understandingpregnancy.biz
- **Premenstrual dysphoric disorder (PMDD)** see www.understandingpmdd.com

When is menopause official?

Menopause occurs when you have not had a menstrual period for 12 consecutive months, barring other complications that would suppress your period, such as prolonged breast feeding, starvation, intense exercise or anorexia nervosa.

Your doctor needs to verify your blood levels of follicle stimulating hormone (FSH), estradiol, luteinizing hormone (LH) and thyroid stimulating hormone (TSH) to make a conclusive diagnosis. FSH is a hormone produced by the pituitary gland in your brain that tells your ovaries to release an egg. When you are perimenopausal and anovulatory, your FSH will increase. For detailed information on menopause see www.understandingmenopause.info.

What are the pros and cons of natural progesterone treatment versus synthetics progestins?

Naturally occurring hormones (progesterone, testosterone and estradiol) when incorporated into a cream are absorbed through the skin (transdermally), so they avoid first-pass metabolism by the liver. First-pass metabolism is a phenomenon where ingested drugs are absorbed through the stomach and intestine, travel to the liver, and are broken down to the extent that only a small fraction of the active drug circulates to the rest of the body. Synthetic forms of progesterone are called progestins (also progestagens). Progestins (such as medroxyprogesterone acetate (MPA), norethisterone, levonorgestrel, drosperinone and desogestrel) are rapidly metabolized by the liver due to the first-pass effect, so the amount of hormone received is significantly reduced. All progestins have side-effects not usually associated with natural progesterone. For example medroxyprogesterone acetate has a very narrow spectrum of action on the uterus and unlike progesterone has significant side-effects. It is sold as Provera® as well as under many generic brand names and is commonly used to treat heavy menstrual bleeding and in hormone replacement therapy. Medroxyprogesterone acetate (MPA) may cause

birth defects if taken during pregnancy. Natural progesterone is the essential hormone of pregnancy. MPA passes into breast milk, so it is not suitable as a treatment for postnatal depression. MPA increases the risk of blood clots, especially in smokers, can cause depression, suicidal feelings, and dementia. It predisposes women to breast, ovarian, and uterine cancer. If medroxyprogesterone acetate is used long-term, it increases the risk of stroke and heart attack. Published side-effects of synthetic medroxyprogesterone acetate include weight gain, itchy skin rash, acne, hair loss, insomnia, bloating, menstrual irregularities, vaginal discharge and tender breasts.

Progesterone receptors in the body are extremely fussy as to what "key" switches it on. Progestins such as MPA **do not** interact with the progesterone receptor in the same way that bio-identical progesterone does and therefore the estrogen dominant symptoms do not respond to a progestin in the same way they do to natural progesterone.

In Summary: Progestins and natural progesterone are worlds apart in their effect and can never be compared for overall effect in treating estrogen dominance.

What is the role of progesterone in humans?

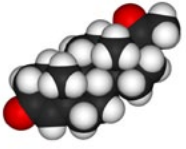
Progesterone is the hormone that regulates menstruation, supports pregnancy, tempers the highly stimulatory effects of estrogen and helps an embryo develop by providing a source of corticosteroids. Natural progesterone is a steroid hormone derived from cholesterol and is vital as a precursor hormone 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.

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.

What are the side-effects of progesterone replacement therapy?

PROFEME® natural progesterone cream has very low toxicity. Progesterone is the hormone that supports a pregnancy ('pro' means for and 'gestation' means pregnancy). The most common problems associated with progesterone treatments are that they can cause symptoms similar to pregnancy:

- Tender breasts
- Fatigue
- Mood swings
- Constipation or diarrhoea
- Headache
- Muscle or joint pain
- 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.

For comprehensive information on the safe and effective use of progesterone in women view www.profeme.com or download the booklet below.

Natural Progesterone Cream Information Booklet (630kb)

What is the role of testosterone in humans?

Natural testosterone is a steroid hormone, normally produced by the Leydig cells in the testes of males and the ovaries and adrenal glands of females. Females produce between 5-10% the daily amount of testosterone that males do. The small amount of testosterone present in females does not have a masculinizing effect. Testosterone increases libido and affects mood in both sexes.

In women, as with men, testosterone plays a crucial role in sexual motivation (libido), energy levels, mood and bone metabolism. When testosterone production declines, libido and energy levels often diminish. Supplementing small amounts of testosterone will restore blood levels to normal levels and usually symptoms resolve. Generally, testosterone is not given to girls until they are physically fully matured and adults. In women, testosterone levels are at their highest around the age of 20 years. Levels steadily fall with age and at the age of 40 years women's serum testosterone levels are approximately half what they were at age 20. This level continues to fall with age. In a perimenopausal woman low sexual desire, unexplained fatigue and lack of energy are commonly due to low testosterone. ANDROFEME® 1% testosterone cream for women treats low libido and low energy in women. Start with 5 mg (0.5 ml) applied once daily to either the inner arms or upper outer thighs. It is important that after three weeks use, blood testosterone levels are monitored (and if necessary adjusted) to maintain blood levels within the normal physiological range for women.

For comprehensive information on the safe and effective use of testosterone in women see www.androfeme.com or click on the link below to download the booklet, The Safe and Effective use of Testosterone in Women.

ANDROFEME® Prescribing Information and Consumer Medicine Information can be downloaded from www.androfeme.com

Testosterone for Women Information Booklet [215 kb]

Understanding Low Libido in Women Information Booklet [1.3 mb]

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 chasteberry (Vitex agnus castus) doesn't 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. Chasteberry 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 chasteberry and Monk's Pepper because it was used for centuries to reduce libido. Do not use chasteberry if you are pregnant, breast feeding, 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 longfolia) and Mucuna Pruriens Extract have not been shown in scientific testing to increase blood testosterone levels despite extravagant marketing claims. Inform your doctor and pharmacist that you are taking any of these or other pharmaceutical or herbal preparations before starting any new medication to avoid adverse drug interactions.

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.

PROFEME® 3.2% progesterone cream is used to control the symptoms of breast disorders during premenstrual syndrome (PMS), menopause, and perimenopausal symptoms. PROFEME® treats other progesterone-deficiency conditions, like surgical menopause 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 needs to be supported with natural progesterone to prevent symptoms of estrogen dominance.

Perimenopausal and menopausal women can evaluate improvement in their symptoms when using PROFEME® progesterone cream using the online Progesterone Deficiency Symptoms Assessment questionnaire at www.understandingperimenopause.com. Ideally the questionnaire should be taken before starting PROFEME® and again after 3 months of treatment.

Symptoms	None	Mild	Moderate	Severe
Water Retention/bloating/weight gain	○	○	○	○
Increased facial hair	○	○	○	○
Breast tenderness/swelling	○	○	○	○
Pain: Headache/migraine/low back/muscle ache/joint ache	○	○	○	○
Vaginal dryness/pain/itching	○	○	○	○

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.

- **Pre-menstrual 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 Post partum 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 can increase frequency to 3 week in 4 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, apply 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® Prescribing Information and Consumer Medicine Information can be downloaded from www.hormonesolutions.com.au

Why is PROFEME® progesterone cream and ANDROFEME® testosterone 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® and ANDROFEME® creams are guaranteed stable, effective, and potent in addition to being the world's only pharmaceutical grade testosterone and progesterone creams. The final products have detailed documentation and are backed by clinical trials that substantiate their therapeutic claims.

2. **Cosmetic Grade:** This is the product 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.

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.

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).

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.

Our Mission Statement

Lawley Pharmaceuticals (www.lawleypharm.com.au) strives to provide the optimal delivery systems for the administration of naturally occurring hormones to counter endocrine deficiency states.

Our philosophy is based on the principle 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 using natural hormones.

Our goal is to establish, through evidence-based medical research, naturally occurring hormones as cornerstone treatments for diseases such as breast cancer, infertility, first-term miscarriage, male hypogonadism, 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

1. Effect of sequential transdermal progesterone cream on endometrium, bleeding pattern, and plasma progesterone and salivary progesterone levels in postmenopausal women. Wren BG et al. Climacteric 2000 3:155–160.

2. Distribution and metabolism of topically applied progesterone in a rat model. Waddell B and O'Leary PJ. J Ster Biochem & Mol Biol. 80 (2002) 449–455.

3. Plasma and saliva concentrations of progesterone in pre- and post-menopausal women after topical application of progesterone cream. O'Leary P 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 ANDROMEN®FORTE 5% cream for androgen replacement in hypogonadal men. Long-Term Pharmacokinetics and Clinical Efficacy of Andromen® Forte 5% Cream for Androgen Replacement Therapy 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.

6. The pharmacokinetics pilot study of ANDROFEME®1% testosterone cream following two week, once daily application in testosterone deficient women. Eden JA et al. Presented at the 4th Annual Congress of the Australasian Menopause Society held in Adelaide 5-7th November 2000.

7. A double-blind, randomized, placebo-controlled trial of the effect of testosterone cream on the sexual motivation of menopausal hysterectomized women with hypoactive sexual desire disorder. El-Hage et al Climacteric 2007; 10: 335–343.

8. Pharmacokinetics Of Andromen Forte 5% Cream: A Dose Finding Study. Kelleher S et al. ANZAC Research Institute, Department of Andrology, Concord Hospital, Sydney, 2002.

Internet Education Reference Sites

www.androforte.com

www.androfeme.com

www.profeme.com

www.natragen.com

www.hormonesolutions.com.au

www.hormonesolutions.com

www.understandingandropause.com

www.understandinganovulation.com

www.understandingbenignbreastdisease.com

www.understandingbreastdisease.com

www.understandingbreastdisorders.com

www.understandingcastration.com

www.understandingdub.com

www.understandingdysfunctionaluterinebleeding.com

www.understandingdysmenorrhea.com

www.understandingdyspareunia.com

www.understandingearlymenopause.com

www.understandingendometrialhyperplasia.com

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www.understandinglowlibido.com

www.understandinglowlibidoinwomen.com

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www.understandingmenopause.biz

www.understandingmenopause.info

www.understandingmenorrhagia.com

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www.understandingmoodchanges.com

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www.understandingovariancysts.com

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www.understandingperimenopause.com

www.understandingpmdd.com

www.understandingpolycysticovariansyndrome.com

www.understandingpostnataldepression.com

www.understandingpostpartumdepression.com

www.understandingpregnancy.biz

www.understandingpremenstrualsyndrome.com

www.understandinguterinefibroids.com

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).

ßhCG: 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 due to overstimulation from environmental and/or supplemented pharmaceutical estrogens including the Pill and HRT.

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.

Symptom Tracker

Symptom Tracker Check off your symptoms √														
Day	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
Period = P														
Can't concentrate														
Crying														
Depressed														
Headache														
Heavy bleeding														
Hot flashes														
Insomnia														
Joint/muscle pain														
Mood swings														
Night sweats														
No libido														
Painful intercourse														
Poor memory														
Tense/irritable														
Tired														
Vaginal dryness														
No period														
Other														
Other														

Symptom Tracker

Symptom Tracker Check off your symptoms √														
Yes, I think I ovulated on Day ____ No, I think I did not ovulate this cycle ____														
Day	*15*	*16*	*17*	*18*	*19*	*20*	*21*	*22*	*23*	*24*	*25*	*26*	*27*	*28*
Period = P														
Can't concentrate														
Crying														
Depressed														
Headache														
Heavy bleeding														
Hot flashes														
Insomnia														
Joint/muscle pain														
Mood swings														
Night sweats														
No libido														
Painful intercourse														
Poor memory														
Tense/irritable														
Tired														
Vaginal dryness														
No period														
Other														
Other														

Copyright Information

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