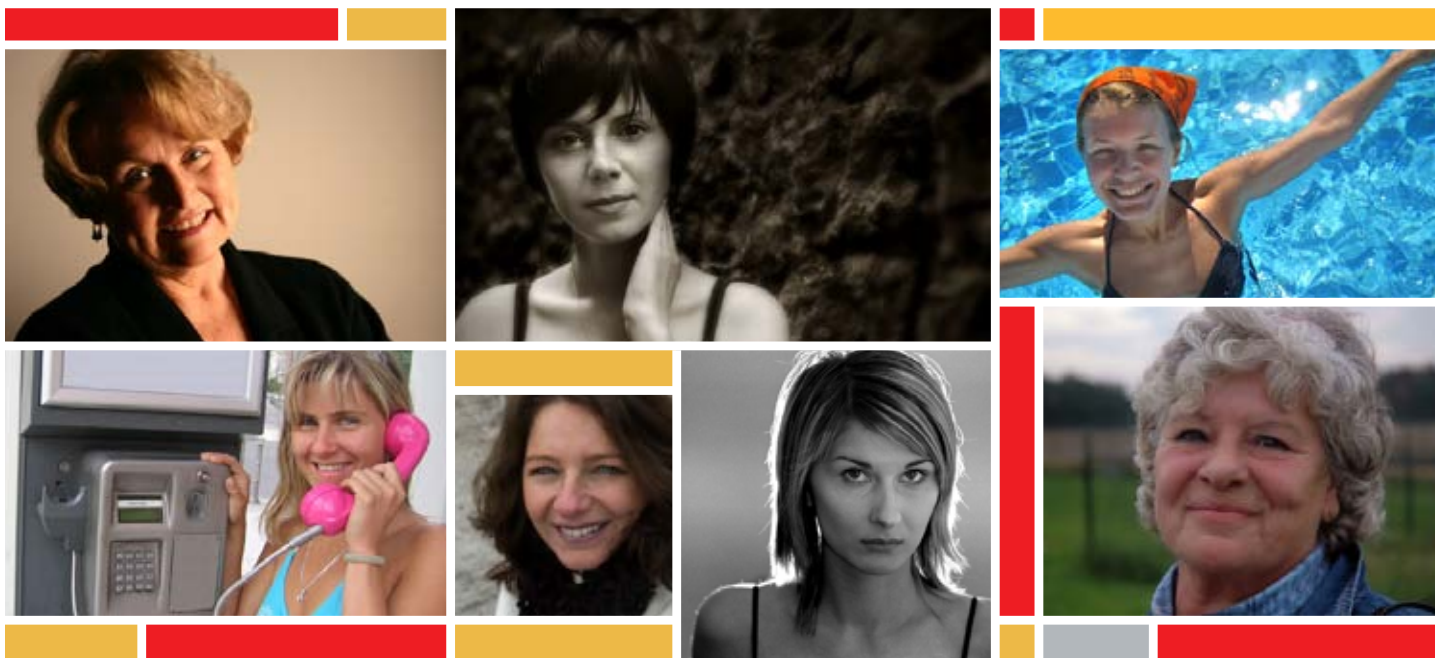


Natural Progesterone Cream

Information for women on the safe and effective use of the hormone progesterone



LAWLEY

Hormone Solutions

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Natural Progesterone Cream – an Introduction

Natural progesterone cream (ProFeme®) contains the naturally occurring hormone progesterone. Progesterone is a pivotal hormone in the endocrine system of women. Progesterone is vitally important for reproduction, regulation of the menstrual cycle and for providing a balance to the stimulatory effects of estrogens. When women do not produce sufficient progesterone the changes that result can severely disrupt the quality of life of those affected. Mood changes, anxiety, depression, weight gain, irregular periods, headache, migraine, infertility, miscarriage, premenstrual syndrome (PMS), post partum depression, endometriosis and polycystic ovarian syndrome (PCOS) are some of the medical conditions associated with reduced progesterone production.

Natural Progesterone - A History

Natural progesterone is a term used to describe the hormone progesterone that is naturally produced by the ovaries of humans and animals. This hormone is not produced anywhere in the plant kingdom.

Progesterone was discovered and isolated in the early 1930's. Initially it was obtained from the ovaries of pigs and later from human placentas. Both these methods were expensive and only yielded small quantities of progesterone.

In 1938 an American biochemist named Russell E. Marker manufactured progesterone in a laboratory by converting diosgenin, found in the Mexican Wild Yam, into progesterone through a series of chemical changes. The soya bean contains the steroid substrate sigmasterol which is also easily converted into progesterone. Soon after this breakthrough, pharmaceutical companies took progesterone and changed it again to give progestins, also called progestagens. These are compounds with actions similar in some respects to progesterone, but not naturally occurring and therefore patentable.

Since the 1940's soya beans, wild yams and other plants from the tuber family have been used to make progesterone. It is very important to understand that soya beans and wild yams **DO NOT** contain progesterone. Today, progesterone is produced for pharmaceutical purposes in the laboratory. The vast majority of steroid substrate for progesterone synthesis is sourced from soya because it is grown in large commercial quantities.

In the early 1990's US medical practitioner, Dr John Lee M.D. pioneered and published books on the benefits of natural progesterone to manage menopausal symptoms, premenstrual syndrome and breast cancer. Dr Lee coined the phrase "natural progesterone" to distinguish real progesterone from progestins, because natural progesterone has such a dynamic and wholistic action on the body whereas progestins have an extremely limited spectrum of action. Unfortunately, because of the development and controlled evolution of progestins by the pharmaceutical industry, mainstream medicine does not make the important differentiation between natural progesterone and the synthetic progestins. The lack of understanding by many medical practitioners of this basic point of difference has been the source of great controversy for many years in scientific circles.

Research has shown that progesterone is most effectively absorbed and utilized by the human body when applied as a cream. It is not as effective when taken by mouth because the liver breaks it down before it can exert a strong effect in the body. Over-the-counter remedies for hormonal imbalances may contain wild yam extracts or homeopathic progesterone, but neither of these contain

pure natural progesterone. In the USA some over-the-counter products do contain progesterone, but often the amount of progesterone contained within these products is insufficient to have any meaningful effect on progesterone deficiency states, and often has minimal effect on managing symptoms of natural progesterone deficiency. Only progesterone creams made to pharmaceutical standards with high quality pharmaceutical grade natural progesterone are guaranteed to provide meaningful amounts of natural progesterone. PROFEME® natural progesterone cream (Lawley Pharmaceutical, Australia) meets these manufacturing and quality standards. Compounding pharmacies do not maintain the exceptionally high and rigorous standards of manufacture that are required to produce pharmaceutical grade products and therefore compounded products' integrity and stability are not the same as pharmaceutically manufactured progesterone products.

Homeopathic progesterone products and wild yam creams contain **NO** progesterone.

Natural Progesterone Deficiency and Estrogen Dominance

Menopause is a stage of life that all women go through. In clinical terms it begins when the woman stops ovulating and menstruation ceases. This usually takes place between the ages of 45 to 55. At this time the ovaries which have been regularly releasing estrogen and progesterone slow down their production of these hormones.

The hormones estrogen and progesterone have a very close relationship. Estrogen is a very stimulatory hormone and natural progesterone tempers the stimulatory effects of estrogen. The effects of natural progesterone and estrogen are summarized in the list below.

ESTROGEN EFFECTS	PROGESTERONE EFFECTS
Builds up uterine lining (proliferation)	Maintains uterine lining (secretory)
Stimulates breast tissue	Protects against fibrocysts
Increases body fat	Helps use fat for energy
Salt and fluid retention	Diuretic
Depression, headache/migraine	Anti-depressant
Interferes with thyroid hormone	Facilitates thyroid hormone action
Increases blood clotting	Normalizes blood clotting
Decreases libido	Restores libido
Impairs blood sugar control	Regulates blood sugar levels
Increases risk of endometrial cancer	Protects from endometrial cancer
Increases risk of breast cancer	Probable prevention of breast cancer
Slightly restrains bone loss	Stimulates bone building
Reduces vascular tone	Propagates growth of embryo
	Precursor of corticosteroid production

With the onset of menopause and the cessation of menstrual periods, estrogen blood levels are reduced, however because there is no ovulation there is also **zero** progesterone production. Reduced estrogen with even lower progesterone leads to an imbalance. This unbalanced decline in hormonal levels can lead to many women experiencing a variety of unpleasant symptoms - what Dr John Lee called [estrogen dominance](#).

For detailed information on estrogen dominance see www.understandingestrogendominance.com

Estrogen Dominance and the Menopausal and Peri-menopausal years

Menopausal symptoms that are the result of estrogen dominance include sleep disturbances, mood swings, irritability, weight gain, lack of energy, malaise, forgetfulness, cloudy thoughts, anxiety or panic attacks, sore bones and general aches and pains. Not everyone will experience all of these symptoms; however, even one or two can be difficult to cope with if not addressed adequately. Correcting any imbalance between the hormones estrogen and progesterone, especially the lack of progesterone, will usually rid an individual of many of these symptoms within a few months. The menopausal symptoms that respond to small doses of estrogen are hot flashes, night sweats, vaginal dryness and poor bladder control. Often if these symptoms are mild then using natural progesterone alone can achieve improvement without having to use estrogens.

For many women, the years prior to menopause ([peri-menopausal](#)) can be more distressing than the actual [menopause](#) itself. During the peri-menopausal years the frequency of ovulation becomes inconsistent or ovulation ceases altogether ([anovulation](#)). As a consequence, progesterone production is variable and minimal. The result of this reduction of progesterone is the unwanted symptoms of [menstrual irregularities](#), mood changes, unexplained fatigue, reduced clarity of thought, loss of motivation and [reduced sexual desire](#). Irregular or shorter intervals between periods, spotting, extended and heavy bleeding are all indicators of progesterone deficiency and estrogen dominance. Peri-menopausal symptoms are commonplace in women during their mid thirties and early forties. This creates a great deal of anxiety, inconvenience and confusion for many women. The long-held belief has been that these conditions and feelings are due to estrogen deficiency; however, it is now apparent that progesterone plays an active role in preventing these changes from occurring prematurely. If there is a menstrual blood flow (regular or irregular) then there is plenty of estrogen being produced by the ovaries. It is estrogen that stimulates growth of the uterine lining. It is progesterone that holds the uterine lining together. If there is a deficiency of progesterone then the uterine lining breaks down; hence irregular and heavy bleeds result.

ESTROGEN DOMINANCE <http://www.understandingestrogendominance.com/>

PERI-MENOPAUSE <http://www.understandingperimenopause.com/>

MENOPAUSE <http://www.understandingmenopause.com>

ANOVLATION <http://www.understandinganovulation.biz/>

MENSTRUAL IRREGULARITIES <http://www.understandingdysfunctionaluterinebleeding.com/>

REDUCED SEXUAL DESIRE <http://www.understandinglowlibido.com/>

Often [peri-menopausal](#) women exhibiting symptoms are prescribed the Pill to “stabilize the hormones.” The Pill overrides the natural hormone production of women and in the case of the peri-menopause adds estrogen but fails to address the progesterone deficiency because the Pill doesn’t contain natural progesterone. Often peri-menopausal women who take the Pill find their symptoms worsen rather than improve. This is due to the added estrogen of the Pill not being balanced by natural progesterone and [estrogen-dominant](#) symptoms are exacerbated. The progestin in the Pill does not do what natural progesterone does in terms of balancing the effects of estrogen and therefore the Pill usually aggravates symptoms in an already estrogen-dominant woman.

The alternative offered to the Pill is often [hysterectomy](#) (removal of the uterus) and this may or may not include removal of the ovaries ([oophorectomy](#)).

[Hysterectomy](#) makes no difference to the way the estrogen/progesterone balance should be viewed. Hysterectomy will certainly stop irregular bleeds and heavy blood loss, but does nothing to address the underlying problem of estrogen dominance due to progesterone deficiency. Addressing imbalances in these women is crucial in order to eliminate unwanted menopausal effects, be they natural imbalances or induced imbalances due to estrogen-only hormone supplementation.

In estrogen dominant peri-menopausal and menopausal women the first line of treatment should always be progesterone cream supplementation. Giving the Pill is giving the wrong hormone. A woman still getting a bleed (regular or irregular) is producing sufficient estrogen. It is the progesterone that is in deficiency and not estrogens. The medical profession has for decades been convinced by the pharmaceutical industry that women are estrogen-only entities and that progesterone is a nebulous hormone. The truth is that progesterone is produced by the body in quantities a thousand-fold greater than estrogens. Progesterone is a pivotal hormone for the propagation of life and for the production of other hormones, including estrogens, glucocorticoids and corticosteroids. Without progesterone there would be no menstrual cycle or reproduction. Progesterone has its own distinct and active role to play in the body including keeping the stimulatory effects of estrogen under control.

Natural Progesterone - Treatment Options

- Hot Flashes and Night Sweats
- Irregular and Heavy Menstrual Bleeding
- Breast Disorders
- Depression and Anxiety Attacks
- Pre Menstrual Syndrome (PMS)
- Post Partum Depression
- Infertility
- Hormone Induced Headache and Migraine
- Breast Cancer
- Endometriosis
- Polycystic Ovarian Syndrome (PCOS)

Hot Flashes and Night Sweats

[Hot flashes](#) and [night sweats](#) are probably the most common and distressing problem that women face when going through menopause. These can last from a few seconds to several minutes and can be accompanied by heavy unabated sweating. When they happen at night (sweats) they can disturb sleep and cause serious fatigue and depression. The whole menopause management

industry began in the late 1950's because hot flashes and night sweats were relieved by taking estrogen. It works and works well for these two symptoms. Estrogen supplementation quickly became the frontline treatment of menopausal symptoms courtesy of the pharmaceutical companies' massive advertising campaigns and has remained so ever since. In the late 1960's a massive surge in cases of uterine cancer was directly attributed to unopposed estrogen use and more recently (2002) the issue of increased risk of breast cancer with long-term estrogen use has highlighted estrogen's checkered history. Many women find that their hot flashes reduce and their night sweats diminish with estrogen supplementation only to be replaced with the estrogen dominant symptoms of anxiety, depression, palpitations, loss of confidence, mood changes and irritability. This is simply because supplementing estrogen without balancing the effects with natural progesterone increases the underlying hormonal imbalance. Remember, menopause is the time when ovulation ceases and if there is no ovulation there is NO progesterone production. Many women find that at the time of menopause, supplementing progesterone rather than estrogen improves the estrogen-dominant symptoms. As well as providing some relief from hot flashes and night sweats, it narrows the imbalance between the hormones. For detailed information on hot flashes and night sweats see www.understandinghotflashes.com and www.understandingnightsweats.com

Irregular and Heavy Menstrual Bleeding

In the U.S. 250,000 hysterectomies are performed annually.

Frequently, hysterectomy is the option taken to control irregular or heavy bleeding in perimenopause. Many women are content to see the end of their periods and hysterectomy appears to be an easy, quick and clean option. Hysterectomy for irregular and/or heavy bleeding is a medical response to a symptom rather than the treatment of the underlying cause. Progesterone's role in a reproductive woman is to hold the uterine lining together during the second half of the menstrual cycle (the luteal phase). Too frequently, natural progesterone treatment is an untried option prior to undertaking hysterectomy. Irregular bleeding in pre and peri-menopausal women is more often than not due to insufficient progesterone production. These irregular and/or heavy bleeds are due to estrogen dominance. Using natural progesterone during the luteal phase of the cycle will usually regulate and control bleeding within two or three months. It is important that uncontrolled bleeding be fully investigated by a gynecologist to exclude serious underlying uterine disease.

Hysterectomized women who also undergo bilateral oophorectomy (removal of both ovaries) are traditionally given estrogen-only supplementation after surgery to manage the immediate onset of menopausal symptoms. Supplementation of the natural hormones progesterone and testosterone is largely ignored by mainstream medicine. Balance with natural progesterone and natural testosterone and estrogen in these women is the only way to fully address surgically

PERI-MENOPAUSAL <http://www.understandingperimenopause.com/>
ESTROGEN DOMINANT <http://www.understandingestrogendominance.com/>
HYSTERECTOMY <http://www.understandinghysterectomy.com/>
OOPHORECTOMY <http://www.understandingoophorectomy.com/>
HYSTERECTOMY <http://www.understandinghysterectomy.com/>
POLYCYSTIC OVARY SYNDROME (PCOS) <http://www.understandingpcos.com/>
HOT FLASHES <http://www.understandinghotflashes.com/>
NIGHT SWEATS <http://www.understandingnightsweats.com/>

induced menopausal symptoms. A three legged stool is useless without all three legs - estrogen, progesterone and testosterone!!! For detailed information on heavy and irregular bleeding see www.understandingheavyperiods.com, www.understandingirregularbleeding.com or www.understandingdysfunctionaluterinebleeding.com and on hysterectomy see www.understandinghysterectomy.com.

Breast Disorders

Breast tenderness, fibrocystic breasts and swollen breasts are all classical symptoms of estrogen dominance. Breast tissue is very responsive to hormone changes and extremely sensitive to estrogens. It is well understood that when women start using the Pill or commence hormone replacement therapy (HRT) they will often complain of the breasts getting bigger, fuller and tender. Breast tissue proliferates (grows) under the influence of estrogen. It is estrogen that stimulates the development of the breasts and reproductive organs during puberty in young girls. In a normal healthy adult female the stimulatory effects of estrogen are tempered and balanced by the hormone progesterone. Progesterone is produced once ovulation takes place around day 12 of the menstrual cycle. Estrogen and progesterone levels peak around day 22 of the menstrual cycle. When a woman does not produce sufficient progesterone the effects of estrogen on the breast are unopposed and the breast tissue is affected.

This is typified by painful and swollen breasts in the week pre-menstrually. It is a sure sign that there is a progesterone deficiency and the addition of progesterone from days 12 -26 of the cycle will balance the estrogen dominance. Resolution of these symptoms usually is maximized in the third month of treatment. For detailed information on hormone-based breast disorders see www.understandingbenignbreastdisorders.com or www.understandingfibrocysticbreasts.com.

Depression and anxiety attacks

During the peri- and early menopausal years, mood swings, anxiety attacks and depressive thoughts are common. Interrupted sleep, loss of libido, body shape changes, crying spells, irritability, low tolerance and feelings of being "old and past it" are further experiences of menopause. Mixed emotions at this time are normal and women need to be reassured they are not "losing their marbles". These feelings are a reaction to what is happening to the body both physically and hormonally. The emotional swings and physical changes are a reflection of the hormonal revolution occurring within.

Too often, anti-depressants are routinely prescribed to address "mood disorders".

While antidepressants certainly have their place in a medical practitioner's arsenal of treatment options they are usually given to treat the symptom and do not address the underlying cause of the problem.

At the time of the menopause, as at the time of puberty, pregnancy and child birth, women undergo massive hormonal changes. During these pivotal phases, emotions and feelings towards one's self and others can be volatile and complex. Hormones govern the way we think, the way we act and the way we respond. During times of hormonal turbulence, such as peri-menopause and menopause, the imbalance between estrogen and progesterone is of primary importance. Addressing this imbalance is a big step towards resolving many of the emotional symptoms associated with the menopausal transition. Antidepressants can assist in the management

of the symptoms, but have little effect on estrogen dominance and menopausal symptoms - that is the role of natural progesterone. For detailed information on progesterone's role in stabilizing mood, emotion and anxiety see www.understandingperimenopause.com and www.understandingmenopause.info.

Premenstrual Syndrome (PMS)

When a collective of symptoms so variable in their intensity and so widely experienced cannot be adequately categorized or adequately defined by evidence-based medical standards it is generally labeled as a "syndrome". To add confusion to the defining of the condition, PMS does not affect all women nor is it restricted to certain age groups. The common thread to the condition is the timing of symptoms in relation to menstruation, hence the name.

In healthy reproductive women with regular menstrual cycles PMS is typified during the 8-10 days premenstrually, by breast tenderness, mood changes, irritability, fluid retention, headaches and migraines. PMS is a misunderstood and often ignored condition. It can vary from mildly disconcerting transient symptoms to a severe and debilitating condition that greatly affects a woman's quality of life for over a week every month. Symptoms generally disappear at the onset of menstruation. People who have never experienced PMS symptoms often have little empathy or understanding for those experiencing PMS. Families and partners of PMS sufferers often have little or no idea how to respond to the mood swings and symptoms of those affected. Mainstream medicine offers little in the way of effective treatments. It has for decades ignored natural progesterone and the pivotal role progesterone plays.

In a normal healthy adult female the stimulatory effects of estrogen are tempered and balanced by the hormone progesterone. Progesterone is produced once ovulation takes place around day 12 of the menstrual cycle. Estrogen and progesterone levels peak around day 22 of the menstrual cycle and remain high until just before menstruation when both hormone levels fall dramatically, the uterine lining sheds and the period commences.

Women who experience PMS usually are under-producers of progesterone or fail to regularly ovulate ([anovulatory cycles](#)). When a woman does not produce sufficient progesterone the effects of estrogen dominate and premenstrual symptoms flourish. The more sustained the length of time the woman under-produces progesterone, generally the more severe the PMS becomes. PMS is not restricted to younger women. Many women date the onset of their PMS to not long after having a second or third child. Hormonally and physically, pregnancy exerts a massive assault on the female body –especially in women who become pregnant for the first time in their late twenties or thirties. Most women who opt for childbirth in their later reproductive years usually do not spring back into shape hormonally (and physically) post pregnancy. After the pregnancy, once the menstrual cycle returns, ovulation generally recommences. Once the egg is released from the follicle on the surface of the ovary, the follicle changes into what is called the corpus luteum. The corpus luteum makes progesterone. Without ovulation there is no production of progesterone. It is not unusual for women with young children, in their mid to late thirties, to produce less progesterone post-ovulation than compared to their pre-pregnant state. At this age however the ovaries are very efficient at estrogen production, estrogen levels remain high and the platform for [estrogen dominance](#) is formed.

ANOVLATORY CYCLES <http://www.understandinganovulation.com>

ESTROGEN DOMINANCE <http://www.understandingestrogendominance.com/>

PMS, estrogen dominance and progesterone deficiency are integrally linked. The addition of natural progesterone cream from days 12 -26 of the cycle will balance the estrogen dominance. Resolution of the symptoms of PMS usually is maximized in the third or fourth month of treatment, often sooner. In the 1960's the English physician, Dr Katerina Dalton devoted her life to natural progesterone research and use in the management of PMS. Her work at the time was ridiculed by her peers and yet today it still remains the most relevant work done in this forgotten area of medicine. For detailed information on progesterone use in managing PMS see www.understandingpremenstrualsyndrome.com.

Postpartum Depression (PPD)

Progesterone is the most pivotal hormone of pregnancy. Progesterone promotes the pregnancy - pro gestation - hence the name.

During pregnancy, progesterone levels rise from a non-pregnant daily production rate of about 20mg per day to up to 400mg per day. Estrogens also rise during pregnancy, but not to the same degree as progesterone. The placenta is responsible for the massive increase in progesterone production, and takes over progesterone production from the ovaries at around week ten of the pregnancy. Progesterone levels are at their greatest during the third trimester. It is during this time when many women "nest" and "bloom". Clarity of thought, mental acuity, high energy levels, confidence and zeal typify this period of many women's pregnancies. With the birth of the child and the passing of the placenta, blood levels of progesterone fall dramatically. The action of breast feeding has the natural action of inhibiting ovulation and progesterone levels remain very low until the return of ovulation. The "second day blues" is a common and transient phenomenon to the new mother, but the more lasting and pervading depression that can overcome some women is triggered by the huge hormonal withdrawal as a result of the birth.

It seems strange that nature would engineer such a huge hormonal shift. In the animal kingdom many females eat the placenta immediately after the birth. Such an action would seem repugnant to humans, but the placenta is highly enriched with progesterone and mother nature may be assisting the animals more than we humans realize. It is logical that the addition of natural progesterone, postpartum, to women who experience postpartum depression, will assist. Natural progesterone does not interfere with breast milk production and offers a far more reassuring treatment than antidepressants to the new mother. Using progesterone cream post pregnancy minimizes the degree of hormonal shift that takes place with the birth. In more severe cases high dose natural progesterone cream treatment combined with professional counseling to assist with postpartum depression is usually only required for a few months. The results can be greatly rewarding to both mother and child. For detailed information on progesterone in managing postpartum depression see www.understandingpostpartumdepression.com.

Infertility

The only area of mainstream medicine where natural progesterone is routinely used is the area of assisted fertility. Natural progesterone injections, progesterone vaginal gel and high-dose natural progesterone pessaries are used to support the uterus once implantation of a fertilized egg has taken place. This use is limited and highly specialized, but does not cover all facets of infertility. A significant number of women have little trouble falling pregnant, but fail to carry the pregnancy beyond week six to ten. Repeat first-term miscarriage is commonly due to progesterone insufficiency.

In a natural pregnancy, the implantation of a fertilized egg starts a cascade of hormonal triggers. One of the most important of these triggers is for the corpus luteum (the former follicle that released the now fertilized egg) to dramatically increase its production of progesterone. Progesterone is the vital hormone that propagates the pregnancy. The corpus luteum is required to produce sufficient progesterone to maintain the integrity of the uterine lining until the placenta takes over the progesterone production at around week nine or ten to meet the ever increasing progesterone demands of the pregnancy.

The most vulnerable time for miscarriage in women who are low progesterone producers during pregnancy is week six to week ten. If the corpus luteum cannot maintain production of sufficient natural progesterone, the uterine lining breaks down and sheds, resulting in the miscarriage. It is women with a history of week six to ten miscarriage that benefit most from supplementing their natural corpus luteum progesterone production with natural progesterone cream. Ideally, a low dose natural progesterone supplementation can be commenced in the months and weeks preceding conception (days 12-26 of the cycle) until the pregnancy is confirmed, then increase to a daily dose (100mg) to support corpus luteal production. Often, women will use the natural progesterone cream for the full term of the pregnancy.

Sometimes, for reasons unknown in more advanced pregnancies, the placenta can under-produce progesterone and the addition of natural progesterone will maintain the integrity of the uterine lining and assist women to carry full term. Treatment is usually dependent upon how advanced the pregnancy is and prior pregnancy history. For example, if spotting/ bleeding occurs, a high dose (100-200mg) of progesterone cream used twice or three times daily is applied. Consult with your reproductive specialist if using progesterone cream in conjunction with assisted-fertility treatments. For detailed information on the use of natural progesterone in infertility please see www.understandinginfertility.com.biz.

Hormonal-induced Headaches and Migraines

It is common that many women experience headaches or migraines (in the more severe cases) in the days leading up to their periods. The duration and severity of the headache is nearly always directly related to estrogen dominance and insufficient progesterone production. Similarly, many women cannot tolerate the Pill or hormone replacement therapy (HRT) for the same reason. Adding estrogens into a progesterone-deficient woman increases the degree of estrogen dominance and often results in side-effects such as hormone-induced headaches and migraines. Additionally, body aches and pains are usually exacerbated as a result.

The use of pain killers, muscle relaxants and antidepressants do not address the underlying cause of hormone-induced headache and migraine.

The use of a natural progesterone cream (PROFEME®) from day 12-26 of the cycle provides the counter-balance to estrogen dominance and reduces the frequency and severity of cyclical headaches and migraines. For detailed information on the use of natural progesterone in hormone-induced headache and migraine please see www.understandinghormonemigraine.com.

Breast Cancer

Breast cancer is one of the greatest fears that women face when they reach menopause and are offered estrogen-based hormone replacement therapy. The issue of breast cancer and estrogens has been highly publicized in the media in recent years and there is often a great deal of concern

for women when faced with the risks versus the benefits of using estrogen to manage menopausal symptoms. There is probably no single cause of breast cancer. It is most likely that there are a number of triggers - genetic, familial, environmental and even psychological that when combined, stimulate the cancers to become active. Dr John Lee, the pioneer of natural progesterone cream for treatment of menopause, before his death wrote a book called, "What your Doctor may not have told you about Breast Cancer". This work clearly and concisely outlines the vital role progesterone has in the breast and in prevention of breast cancer. It is highly recommended reading. One of the most controversial breast cancer and natural hormone medical studies ever conducted, provides an insight into the profoundly positive effect natural progesterone has on cancerous breast tissue. (Ref: Chang et al) In 1995 a joint French-Taiwanese medical team took 40 women with breast cancer who were scheduled for mastectomy and divided them into four groups. Each group was assigned to a treatment that was either estrogen only (E), estrogen and natural progesterone (E+P), natural progesterone (P) only or placebo (PL). The hormones were administered via a gel that was applied once daily directly to the breasts for ten days prior to surgery. After surgery, the cancerous breast tissue was assayed and the rate of cell division (mitosis) was examined. In breast cancer, as in most cancers, the rate of mitosis of the cancerous cells is more rapid than that for non-cancerous cells, hence the reason why cancers take over healthy cells. When the researchers examined the various cell groups that had been treated with the hormones, the results were astonishing. As was expected, the estrogen-only group's mitotic cell division rate doubled compared to the placebo (untreated) group. The stimulatory effect of estrogen on cancerous breast tissue is well known. The researchers' excitement stemmed from the results of the estrogen plus natural progesterone and the natural progesterone-only groups. The E+P group's mitotic rate was the same as the placebo group. This indicated that natural progesterone had an inhibitory effect upon estrogen stimulating cell growth. The exciting finding was when the progesterone-only (P) group was examined. It was found that the rate of cell division of progesterone-only users was 85% less than the placebo group - **natural progesterone was inhibiting the cell division of the cancer**. Natural progesterone was potentially a potent treatment for breast cancer. This study had its critics. They said the numbers studied were too small to be significant and that the progesterone blood levels of the P and E+P groups did not rise. Therefore, it was considered that the progesterone hadn't been absorbed. When the hormone concentrations of the cancerous cells were examined, the progesterone was found in very high concentrations in both progesterone groups and absent in the E and PL groups. The progesterone had been absorbed directly into the cells and not circulated in the blood. It was acting directly inside the cancerous cells and the mitotic rates proved it.

Larger scale clinical studies have never been conducted to confirm these findings from 15 years ago. With the modern day rigors and political correctness of Ethics and Scientific Committees, the massive funds required to undertake clinical trials and the complex insurance obligations to undertake such trials, it is unlikely that it will be repeated on a larger scale. The pharmaceutical industry's charter is to discover the next blockbuster patentable drug. Natural progesterone does not meet this criteria. The early results are conclusive and natural progesterone cream is available. With time, progesterone may prove to be the missing link in the quest to prevent and treat breast cancer. The challenge is there for mainstream medical researchers and governments to take up.

Ref: Chang KJ et al. Influences of percutaneous administration of estradiol and progesterone as human breast epithelial cells cycle in vivo. Fertil Steril 1995: 785-91.

Endometriosis

Endometriosis is a condition whereby tissue normally located on the surface of the uterine wall (endometrium) migrates into areas such as the muscle tissue of the uterus, the Fallopian tubes, the surface of the ovaries and even into the pelvic cavity and beyond. This tissue is responsive to the surges of estrogen encountered during the menstrual cycle. The tissue will swell during

the month and bleed at the same time of menses. Unlike endometrial tissue (the tissue lining of the uterus) which sheds into the uterine cavity, the endometriosis bleeds into the spaces between cells and has nowhere to go. The condition is painful, often debilitating and greatly hinders fertility. Treatment varies from analgesics (pain killers) to high-dose synthetic progestins to surgical procedures including hysterectomy.

Often pregnancy, if possible, is suggested as the best treatment. During pregnancy, when progesterone levels are high and estrogen relatively low, endometriosis virtually disappears. The very high level of progesterone produced by the placenta during pregnancy suppresses and overcomes the endometrial tissue. Occasionally with the return of menses post-pregnancy, the endometriosis will return.

Endometriosis has various degrees of severity and current treatment is aimed at symptom management. Unfortunately, natural progesterone treatment is rarely offered as an option to patients. Endometriosis is a condition at the extreme end of the scale of estrogen dominance. The underlying cause is progesterone deficiency. Treatment with high dose progesterone cream, even in severe cases usually achieves improvement in the condition. In milder cases often there is a full resolution of symptoms with pain free periods. Depending upon the severity of the endometriosis, the treatment may take three to six months to achieve full benefit. For many women yet to start a family this is a better option than endometrial ablation, hysterectomy or long-term hormonal suppression.

Natural progesterone cream offers a viable alternative to current mainstream endometriosis treatments because it safely tempers the stimulating effects of estrogen. For detailed information on natural progesterone use in managing endometriosis see www.understandingendometriosis.com

Polycystic Ovarian Syndrome (PCOS)

The process of ovulation involves the ovary responding to chemical messengers sent from the brain. The brain controls the chemical signals sent to the ovaries based upon chemical signals it receives back in response to its signals. It's called a feedback mechanism. At birth every female has around 400,000 immature eggs in follicles contained within the ovaries. At puberty the reproductive organs, under the influence of estrogens, mature and a key part in the process of ovulation is that the brain releases the hormones Follicle Stimulating Hormone (FSH) and Luteinising Hormone (LH).

FSH stimulates a number of immature eggs to mature, rise to the surface of the ovary and usually one follicle releases a mature egg into the Fallopian tube - this release is ovulation. The unused semi - mature follicles are broken down and reabsorbed by the body. The follicle that released the egg then undergoes a spectacular metamorphosis. Its entire structure changes and it forms what is called the corpus luteum. Visually the corpus luteum appears as a yellow mass on the surface of the ovary and the corpus luteum plays the vital role of being the production site for progesterone. The progesterone produced by the corpus luteum is released into the bloodstream. As the progesterone concentration in the blood increases this is detected by the brain which in turn shuts off the production of FSH, because it now knows that ovulation has successfully taken place. Without the production of progesterone, the brain thinks that ovulation has failed to take place and will keep producing FSH and LH to stimulate ovulation.

Women with PCOS fail to ovulate and have very few periods in a year. The follicles mature, rise to the surface of the ovary, but for reasons unknown they fail to release. As a result, the corpus luteum doesn't form and no progesterone is produced. The brain doesn't detect any

progesterone rise in the blood and therefore releases more FSH to stimulate more follicles. The surface of the ovary looks lumpy and bumpy with many semi-matured follicles just below the surface, all having failed to ovulate – usually they are arranged in a pearl-necklace formation. Because of this disruption to the normal hormonal cycle PCOS sufferers generally develop higher levels of the hormone testosterone due to increased luteinizing hormone (LH) being released from the pituitary gland in the brain. With time, this has the effect on the PCOS sufferer of weight gain, acne and oily skin, and increased facial and body hair. Associated with these physical changes the body becomes resistant to the effects of insulin and as a result the normal process of sugar metabolism is disrupted. Sugar is converted to fat and the PCOS sufferer usually has significant weight problems. PCOS usually affects younger women and is often undetected for many months and even years. Often, symptoms are associated with the physical maturation of the body and expected to settle down with time.

There are numerous synthetic hormonal and non-hormonal options to treat PCOS which involve management of symptoms rather than addressing a significant underlying cause – progesterone deficiency. The key to management of PCOS is the use of natural progesterone. For detailed information on PCOS see www.understandingpcos.com.

The Progesterone Deficiency Assessment Questionnaire

Quantifying the severity of symptoms can often be difficult because symptoms may vary from day-to-day or week-to-week. What is usually consistent with most women is that they steadily get worse with time which often leads women to seek medical intervention. The Progesterone Deficiency Assessment Questionnaire allows for a baseline assessment of symptoms to be made and provides a valuable tool for the monitoring of whatever method of symptom management a woman chooses to undertake.

The Progesterone Deficiency Assessment Questionnaire is a 15 question self-assessment tool women can use to assess the severity of their symptoms and can be taken online at <http://www.hormonesolutions.com.au/?page=pages/menopause-self-assessment> The Progesterone Deficiency Assessment Questionnaire is free.

Generally women who use PROFEME® progesterone cream to manage the symptoms of estrogen dominance see a 50% reduction in their initial Progesterone Deficiency Assessment score after 3 months use and then another 50% reduction after a further 3 months.

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

What are the pros and cons of natural progesterone treatment versus synthetic 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. This first-pass through the liver greatly reduces the availability of the hormones to cells by breaking them down into less active forms. Synthetic forms of progesterone are called progestins. Progestins (such as medroxyprogesterone acetate (MPA), norethisterone, levonorgestrel, drospirinone 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 brandnames 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 and damages the infant, 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 them 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 it does 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

ESTROGEN DOMINANCE <http://www.understandingestrogendominance.com/>

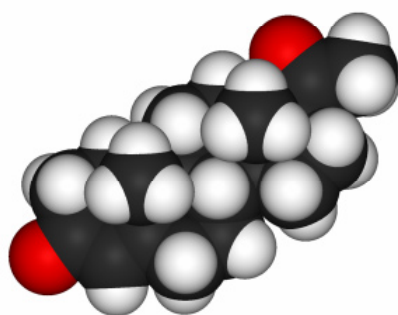
PREGNANCY <http://www.understandingpregnancy.biz/>

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.



Progesterone molecule

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.

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.

EXCESSIVE MENSTRUAL BLEEDING <http://www.understandingheavyperiods.com/>
MISCARRIAGE <http://www.understandingmiscarriage.biz/>
MOOD CHANGES <http://www.understandingmoodchanges.com/>
ANXIETY <http://www.understandingestrogendominance.com/>
DEPRESSION <http://www.understandingestrogendominance.com/>
WEIGHT GAIN <http://www.understandingestrogendominance.com/>
IRREGULAR PERIODS <http://www.understandingperimenopause.com/>
HEADACHE <http://www.understandinghormonemigraine.com/>
MIGRAINE <http://www.understandinghormonemigraine.com/>
INFERTILITY <http://www.understandinginfertility.biz/>
PREMENSTRUAL SYNDROME (PMS) <http://www.understandingpremenstrualsyndrome.com/>
POST PARTUM DEPRESSION <http://www.understandingpostpartumdepression.com/>
ENDOMETRIOSIS <http://www.understandingendometriosis.com/>
PREGNANCY PROBLEMS <http://www.understandingpregnancy.biz/>
BREAST DISORDERS <http://www.understandingbreastdisorders.com/>
POLYCYSTIC OVARIAN SYNDROME (PCOS) <http://www.understandingpcos.com/>

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

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- ESTROGEN DOMINANCE** <http://www.understandingestrogendominance.com/>
 - BENIGN BREAST DISORDERS** <http://www.understandingbreastdisorders.com/>
 - PREMENSTRUAL SYNDROME (PMS)** <http://www.understandingpremenstrualsyndrome.com/>
 - MENOPAUSE** <http://www.understandingmenopause.biz/>
 - PERIMENOPAUSAL SYMPTOMS** <http://www.understandingperimenopause.com/>
 - HYSTERECTOMY** <http://www.understandinghysterectomy.com/>
 - OVARIAN CYSTS** <http://www.understandingovariancysts.com/>
 - UTERINE FIBROIDS** <https://www.understandinguterinefibroids.com/>
 - FIBROCYSTIC BREASTS** <https://www.understandingfibrocysticbreastdisease.com/>
 - HOT FLASHES** <http://www.understandinghotflashes.com/>
 - NIGHT SWEATS** <http://www.understandingnightsweats.com/>
 - ESTROGEN DOMINANCE** <http://www.understandingestrogendominance.com/>

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).

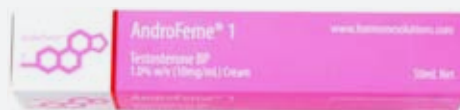
ANDROFORTE® 2, ANDROFORTE® 5 and ANDROFEME® are testosterone creams specifically targeted for use in men and women with declined or lowered serum testosterone levels due to genetic disorders, neurological disorders, surgical or chemical interventions or under-production by the testes or ovaries and/or 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 include:

AndroFeme® 1% testosterone cream for women



AndroForte® 2% and AndroForte® 5% testosterone creams for men



ProFeme® 3.2% and 10% progesterone creams for women



Natragen® 0.2% estradiol cream for women



PROFEME <http://www.profeme.com/>

ANDROFORTE <http://www.androforte.com/>

ANDROFEME <http://www.androfeme.com/>

NATRAGEN <http://www.natragen.com/>

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 sigmasterol - 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 sigmasterol 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 (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 research 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 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 ANDROMEN®FORTE 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.*
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

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
ANOVLATION 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
HYPOGONADISM www.understandinghypogonadism.com
HYSTERECTOMY www.understandinghysterectomy.com
INFERTILITY www.understandinginfertility.biz
IRREGULAR PERIODS www.understandingirregularperiods.com
KLINEFELTER SYNDROME www.understandingklinefeltersyndrome.com
LIBIDO www.understandinglibido.com
LOW LIBIDO www.understandinglowlibido.com
LOW TESTOSTERONE www.understandinglowtestosterone.com
MENOPAUSE www.understandingmenopause.biz
MENOPAUSE www.understandingmenopause.info
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MISCARRIAGE www.understandingmiscarriage.biz

MOOD CHANGES www.understandingmoodchanges.com
NIGHT SWEATS www.understandingnightsweats.com
OOPHORECTOMY www.understandingoophorectomy.com
OVARIAN CYSTS www.understandingovariancysts.com
PCOS www.understandingpcos.com
PERIMENOPAUSE www.understandingperimenopause.com
PMDD www.understandingpmdd.biz
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POSTNATAL DEPRESSION www.understandingpostnataldepression.com
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PREMENSTRUAL SYNDROME www.understandingpremenstrualsyndrome.com
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NATURAL-PROGESTERONE-ADVISORY-NETWORK www.Natural-Progesterone-Advisory-Network.com

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