Understanding hypogonadism

n children and adults



LAWLEY

Hormone Solutions

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What is hypogonadism?

Hypogonadism occurs when the ovaries or testes (gonads) do not produce enough gonadal hormones (progesterone, estrogen, and testosterone). The ovaries or testes atrophy (shrink), so they cannot produce enough germ cells (ova or sperm). Hypogonadism affects the growth of the brain, bone, muscle, fat, body hair, and breasts.

People with hypogonadism can have:

- Memory and concentration problems ('brain fog')
- Thin, brittle bones that break easily
- Abnormal hair and muscle growth
- Low sex drive (libido)
- Sexual dysfunction including a dry, degenerated vagina, impotence, or erectile dysfunction
- Heart and blood vessel disease
- Infertility

Hypogonadism occurs more often in males than in females

The pituitary gland in the brain controls gonadal hormones, which determine the sex of a fetus, when a child matures into an adult, and reproductive function. Primary hypogonadism is a problem with the ovaries or testes. Secondary hypogonadism is a result of a problem with the pituitary gland.

While this booklet covers information on hypogonadism in both adults and children, more specific information pertaining to childhood hypogonadism can be found in the booklet Understanding Childhood Hypogonadism downloadable at www.childrenhormones.com

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When does hypogonadism occur?

People of any age can develop hypogonadism. If a fetus develops hypogonadism, then it may have sexual ambiguity – the genitals may not appear clearly male or female (hermaphrodite). If a child develops hypogonadism, then he or she may not enter puberty. If a young person develops hypogonadism, then he or she will be infertile and may be sexually dysfunctional. Normal hypogonadism happens during menopause, around age 51, when women's production of estrogen and progesterone decreases as the childbearing years end. Many young women are in early menopause because of hysterectomy, kidney failure, cancer treatment, or ovarian failure. Men can develop androgen deficiency (andropause, male menopause, or late-onset hypogonadism) after age 50 and often earlier.

How many people have hypogonadism?

Children

First, a little background: The default sex of an embryo is female. Females have two X chromosomes (XX). Males have an X and a Y chromosome (XY). If a male sperm fertilizes an egg, then the baby will be male. However, if the sex chromosomes are damaged or the androgen hormones are inadequate to stimulate male development, then the child will be sexually ambiguous.

XXY syndrome (Klinefelter Syndrome) is the major cause of primary hypogonadism in males, which occurs in 1 out of every 500 male births in the USA. It is a chromosomal abnormality affecting only boys, where one extra X chromosome is present.

XYY syndrome is another cause of hypogonadism, which occurs in one out of every 1,000 live births. It is a chromosomal abnormality affecting only boys, where one extra Y chromosome is present.

Both male and female children can develop hypogonadism because of Kallman's syndrome (KS). One in 10,000 males has KS. One in 50,000 females has KS. For detailed information see www.kallmanssyndrome.com

Turner's syndrome causes hypogonadism in one out of every 250,000 live births. It is a chromosomal abnormality affecting only girls, where one X chromosome is missing. Turner's syndrome is responsible for 20% of

all miscarriages that occur in the first trimester, and 98% of pregnancies affected by Turner's syndrome end in miscarriage. For detailed information on Turner Syndrome see www.turnersyndrome.us

Adults

In women, menopause is hypogonadism because of normal female ageing. There are about 25 million women in the menopause transition worldwide at any one time. By 2030, about 1.2 billion women will have experienced menopause.

Between 20% - 30% of males older than 46 are androgen deficient, showing symptoms consistent with androgen deficiency yet recent medical research shows most remain untreated.

What causes hypogonadism?

Hypogonadism is caused by:

- Stress
- Trauma
- Excessive dieting (anorexia nervosa)
- Radiation
- Chemotherapy
- · Sickle cell anemia
- Environmental toxins
- Viral orchitis if a male gets mumps after puberty
- Too much prolactin, the milk-producing hormone
- Genetic disorders, like Turner's syndrome or XYY or XXY syndrome
- Disruption of complex female hormone cycling
- Street drugs, like heroin and marijuana
- Prescription drugs, like methadone, spironolactone, and ketokonazole
- · Liver and kidney disease
- · Cancer of the gonads
- Removal of the pituitary gland to treat a pituitary tumor, or breast or prostate cancer
- Diabetes mellitus
- Malnutrition
- Cushing syndrome
- Hemochromatosis
- Alstrom syndrome

• Laurence-Moon Biedl syndrome

This list does not include all causes.

What are the symptoms of hypogonadism?

Males:

If your son developed hypogonadism in the womb, he may have:

- Undescended testicles (cryptorchidism)
- Small penis (micropenis)
- Feminized or ambiguous genitals (hermaphroditism)
- Urethral opening on the bottom of the penis, instead of at the end of the glans (hypospadias)

Genetic disorders such as chromosomal variants 47,XYY and XXY (Klinefelter Syndrome) are the most common form of genetic based hypogonadism. Hypogonadism does not present significant symptoms in most boys until puberty. Suspect XXY or Klinefelter syndrome if your son is taller than 75% of his male classmates, has thin arms and shoulders, severe acne, and is clurmsy and uncoordinated. He will not have any physical abnormalities. If your son does not develop a beard, but does develop enlarged breasts, and you are concerned about his lack of growth, then see your doctor. (See www.andropausesupport.com) Adult males with Klinefelter Syndrome are infertile, tend to be taller than average, have

little body hair, have female-like fat distribution and small underdeveloped testes. In XXY boys and men testosterone supplementation is the gold standard treatment.

Extreme hypogonadism in boys is Frolich's syndrome, eunuchism, or euchnuchoidism. Affected boys are small, obese, and have tiny genitals because of a tumor in the hypothalamus portion of the brain.

Most adult men with XYY syndrome are fertile and have normal sexual function. Some are infertile because of inadequate sperm production. Males with XYY have 40% fewer spontaneous erections, as compared to normal XY males. XYY men have fewer sexual fantasies, decreased sexual desire, and perform fewer sexual acts. Testosterone supplementation can help to remedy the sexual dysfunction. 47,XYY syndrome is associated with an increased risk of learning disabilities and delayed development

of speech and language skills. Delayed development of motor skills (such as sitting and walking), weak muscle tone (hypotonia), hand tremors or other involuntary movements (motor tics), and behavioral and emotional difficulties are also possible. These characteristics vary widely among affected boys and men.

Androgen Deficient Ageing Males (ADAM), or late-onset hypogonadal males, are lethargic from disturbed sleep, depressed, irritable, have muscle weakness, increased fat at the hips and thighs, low energy, unexplainable fatigue, sexual dysfunction, confusion and anxiousness. (see http://www.hormonesolutions.com.au/content/testosterone-cream-formen.php)

Females:

If your daughter developed hypogonadism in the womb, you probably will not suspect it until she fails to reach puberty. Usually it is because of Turner's syndrome. Hypogonadism in girls causes lack of menstrual periods (amenorrhea) and sterility. Suspect Turner's syndrome if your daughter has this appearance:

- Very short (20 centimeters or almost 8 inches shorter than her peers)
- No pubic or underarm hair
- No breast development
- Very widely-spaced eyes
- Low-set ears
- Webbed neck
- Shield-shaped chest
- Droopy eyelids

Your Turner's syndrome daughter may complain of dry eyes and no periods. She may have dental problems, like excessive cavities and plaque. She may demonstrate poor math skills, or another learning disability, and poor spatial

perception. She may have only one kidney, and heart problems with the bicuspid valve and aorta. Turner's syndrome is also called monosomy X, gonadal dysgenesis, or Bonnevie-Ullrich syndrome.

Women with kidney failure, liver disease, or early hysterectomy experience early menopause. Although menopause from ageing is a normal and expected occurrence, it can produce discomfort in the form of hot

flashes, sleep disturbances, memory problems, bladder leakage, sexual dysfunction including low libido and pain during penetrative sex, and fatty deposits around the abdomen. Menopausal discomfort can be alleviated after about two weeks of therapy with natural hormone creams. Natural testosterone cream can address issues relating to sexual dysfunction.

Both Sexes:

Either gender can have Kallman's syndrome. The child has no sense of smell (anosmia) and puberty is delayed. The child does not produce enough luteinizing hormone (LH) or follicle-stimulating hormone (FSH). Boys may produce androgen hormones, but are resistant to their effects, and may have a small penis. Either gender can have cleft lip or cleft palate, impaired vision or hearing, clubfoot, central nervous system problems, and abnormal kidneys. Look for abnormal eye and muscle movements. If your child often tries to make a movement voluntarily and makes an unintended movement instead (synkinesia), then you should have him or her investigated by a doctor.

When should I be concerned?

Visit your family doctor if any of these signs and symptoms develop:

- Slow or no onset of puberty
- Sexual dysfunction
- Headaches
- · Loss of vision
- Breast enlargement in males (see www.understandinggynecomastia.com)
- Lack of breast development in adolescent females
- Milky discharge from the breasts when you are not pregnant or breastfeeding (see www.benignbreastdisease.org)
- Severe weight loss from dieting
- Amenorrhea (lack of menstruation)
- Hot flashes
- · Lack of libido
- Loss of muscle mass and body hair
- Unexplained fatigue, lethargy

Who is most likely to have hypogonadism?

- Type I Diabetics are more likely to develop hypogonadism
- People of African descent have sickle cell anemia, predisposing to hypogonadism
- Type II Diabetic women and girls with juvenile rheumatoid arthritis are more likely to have Turner's syndrome
- Kallman's syndrome affects all races

How can I decrease my symptoms?

Males

You may inadvertently lower your testosterone level by consuming foods containing too much protein and too few carbohydrates. If you go on a fad diet with too many carbohydrates and too little fat, it can deplete testosterone. You can marginally increase your testosterone level with exercise.

To produce enough testosterone, your body requires the:

- Minerals boron and zinc
- Vitamins A. B6, and C
- Branched Chain Amino-acids (BCAA) valine, isoleucine, and leucine

Other factors that may lower testosterone levels include:

- · Acute critical illness, burns, major trauma or surgery
- Drug use (e.g., opiates, glucocorticoids, anabolic steroids, some anticonvulsants)
- Chronic disease and its treatment
- Alcohol abuse
- Smoking
- Ageing

Most of the above cause an increase in Sex Hormone Binding Globulin (SHBG). SHBG is a transporter protein found in the blood. It acts as a carrier to move hormones around the body. Up to 99% of testosterone produced is bound to SHBG. Once bound to SHBG, the testosterone is inactive. Testosterone to which SHBG does not attach is the biologically available testosterone that is free to act on cells throughout the body.

Eat a well-balanced diet, consider taking a dietary supplement containing the above ingredients, and exercise at least three times a week for 20 minutes.

Females

- Stop smoking, as it impairs the functioning of your ovaries
- Keep a menstrual diary, including dates, flow, and moods, so you will know what worsens your symptoms
- Maintain a normal body weight, because obesity predisposes you to fibroid tumors and endometrial hyperplasia, which are uncomfortable and potentially dangerous (See Glossary for details.)
- Use a water-based lubricant for sex, never petroleum jelly
- Avoid spicy food, hot beverages, and alcohol to prevent hot flashes
- · Eat soy food 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
- Ask your doctor for antidepressants
- Dress in layers, so if you feel hot, you can remove some clothing
- Take a dietary supplement containing Vitamin D, calcium, & Vitamin E
- Stay in air conditioned areas
- Consider using PRO-FEME® natural progesterone cream to address symptoms associated with estrogen dominance and progesterone deficiency.

 Most forms of

What are my treatment options?

Menopausal women can effectively control their symptoms using natural progesterone,

hypogonadism are treatable

testosterone and estrogen either alone or in combination depending upon individual circumstances.

It is well established that as women transition the menopause progesterone levels decline to zero and estrogen production reduces but does not cease. This leads to an imbalance resulting in what is termed "estrogen dominance". Estrogen dominance is typified by symptoms including sleep disturbances, poor bladder control, mood swings irritability, weight gain, lack of energy, malaise, forgetfulness, cloudy thoughts, anxiety or panic attacks, reduced sexual motivation, 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. Australian company Lawley Pharmaceuticals

(www.lawleypharm.com.au) produce the world's only pharmaceutical grade and clinically trialed progesterone cream, PRO-FEME®.



PRO-FEME® safely and effectively reduces the menopausal symptoms by replacing the hormone of greatest deficiency and opposing estrogen dominance. To find out more about estrogen dominance see www.estrogendominance.info.

PRO-FEME® achieves a steady state of hormone balance after 6 – 8 weeks of regular use. Women who take synthetic progesterone pills (eg. Provera®) often develop unpleasant side effects, such as: weight gain; severe depression, tension, and anxiety and glucose intolerance.

Women can use testosterone to treat poor libido and unexplained fatigue. This is a common "off-label" practice among doctors in the USA and parts of Europe, where no testosterone product is officially approved for use by women. The situation in Australia is distinctly different. Lawley Pharmaceuticals produce a 1% testosterone cream (ANDRO-FEME®), tailored especially for women. ANDRO-FEME® 1% testosterone cream for women is by far the most user friendly testosterone treatment option for use in women because it involves no surgery, no pain or visible patches and is applied by the woman in the privacy of her own home, and the dose is accurately controlled and adjustable. For detailed advice on the use of testosterone in women see www.hormonesolutions.com.au



Natural estrogen (estradiol) in the form of a gel, transdermal patch or implant is more beneficial than tableted dose forms of synthetic estrogens for short-term management of hot flashes.

Detailed information for the use of progesterone and testosterone for the management of menopausal symptoms in women is available at www.menopauseandhormones.info. The booklet entitled Menopause can also be downloaded from the Hormone Solutions website.

Adult men with XYY, XXY and many other hypogonadal conditions can improve their sexual function with testosterone cream, patches, or injections. Oral testosterone is synthetic, not as effective and is dangerous to the liver. In recent years treatment for hypogonadal males has shifted from injectable forms of testosterone to topical application to the body (for testosterone patches and gels) or directly to the scrotum for testosterone creams.

The use of natural testosterone combats their:

- Changes in mood (fatigue, depression, anger)
- Decreased body hair (feminization)
- Decreased bone mineral density and possible resulting osteoporosis
- Decreased lean body mass and muscle strength
- Decreased libido and erectile quality
- Increased abdominal fat
- Rudimentary breast development (man boobs or gynecomastia)
- Low or zero sperm in the semen (azoospermia)

Lawley Pharmaceuticals produce a 5% testosterone cream, ANDROMEN® FORTE, which is applied scrotally once daily. ANDROMEN® FORTE usually takes two weeks for the testosterone levels to stabilize and a significant improvement in symptoms is usually achieved within a month of commencing treatment.

Both sexes have difficulty developing or maintaining their secondary sexual characteristics if they do not have adequate gonadal hormones. Delayed puberty means males and females will have difficulty fitting in with their peers because they look immature and childish. Adolescents with hypogonadism may benefit from counseling and a peer support group. Adult men and women with sexual dysfunction may benefit from psychotherapy, sex therapy, and fertility treatments.

Girls who do not produce enough estrogen or progesterone are given hormone supplements, usually oral, skin patches, or injections. Estrogen must be balanced with progesterone, because taking estrogen alone leads to a dangerous build up of the lining of the uterus (endometrial hyperplasia) that can lead to cancer of the uterus. Hypogonadal girls need estrogen based hormone replacement therapy until age 50, when they would normally experience menopause. Hormone replacement is vital to prevent bone fractures in Turner's syndrome women.

Kallman and Turner syndrome have no cures. They are permanent genetic disorders. Hormone replacement therapy including testosterone controls symptoms.

For all other causes of hypogonadism, the doctor must treat the underlying condition, for example, diabetes, drug abuse, or sickle cell anemia. Treatment is tailored specifically to the condition, and often requires specialists. For example:

- A dieter with anorexia nervosa needs multifaceted treatment at an eating disorders clinic with an endocrinologist, psychologist, and nurse specialist.
- If a tumor is causing your hypogonadism, you will need surgery and/or chemotherapy to remove it.

What are the pros and cons of natural hormone treatments versus synthetics?

The naturally occurring hormones 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 bioavailability of the hormones by breaking them down into less active forms. Synthetic hormone pills (such as medroxyprogesterone acetate, estradiol valerate and methyltestosterone) are rapidly metabolized by the liver on the first pass, so the amount of hormone received is significantly reduced. Most synthetic hormones have side effects not usually associated with naturally occurring hormones. For

example methyltestosterone is highly damaging to the liver. Oral hormones are excreted in the urine, so most of your dose is lost. Bio-identical, also called, natural hormones are identical to those produced by the ovaries and testes. If one believes the body responds best to the hormones it naturally produces then it seems logical to supplement the identical hormones that are lacking rather than synthetic analogues. Provided the doses of bio-identical hormones are monitored they can be used safely and effectively without the severe range of side effects associated with many synthetic hormones.

An Australian company, Lawley Pharmaceuticals www.lawleypharm.com.au, specialises in pharmaceutical grade manufacturing of natural hormone creams.

Lawley Pharmaceuticals products include ANDROMEN® and ANDROMEN® FORTE testosterone creams for males, ANDROFEME® testosterone cream for females and PRO-FEME® progesterone cream for females.

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 (see www.progesteroneinpregnancy.info).

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,



Progesterone molecule

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 one of the hormones that regulate the uterus, gall bladder, thyroid, bones, teeth, skin, ligaments, tendons, and joints.

Women take progesterone to prevent excessive menstrual bleeding and to assist with in-vitro fertilization. A woman with a very short cervix who is prone to miscarriage can take progesterone to help maintain her pregnancies, because it has been proven to reduce pre-term births and the time babies spend in neonatal intensive care units (see www.miscarriage-hormone-treatment.com).

Mood changes, anxiety, depression, weight gain, irregular periods, headache, migraine, infertility, miscarriage, premenstrual syndrome (PMS), post natal 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?

PRO-FEME® 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 diarrhea
- 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 see www.hormonesolutions.com.au or click on the link below.

Natural Progesterone Cream Information Booklet [630 kb]



What is the role of testosterone in humans?

Natural testosterone is a steroid hormone, normally produced by the Leydig cells in the testes of humans and animals. Females produce far less testosterone in Testosterone molecule. their ovaries than males do in their testicles. The small amount of testosterone present in females does not have a masculinizing effect. Testosterone increases libido and affects mood in both sexes.

D. Dinneen, July 2008

Testosterone is classified as an androgen (masculinizing substance). Androgens control masculine secondary sex characteristics, like male hair growth patterns (beard, armpits, chest and groin), deep voice, and male fat distribution. Testosterone is crucial for the development and maintenance of the male sex organs (testes and penis). Testosterone is also an anabolic, meaning it encourages bulky, strong muscle growth. Testosterone has systemic anabolic effects. It influences fluid balance by making the male retain electrolytes (sodium, potassium, and chloride), water, and nitrogen. Testosterone influences bone growth by encouraging the retention of calcium and phosphate. Testosterone makes the skin more vascular and less fatty.

What are the side-effects of testosterone replacement therapy in men?

In hypogonadal boys just starting testosterone treatment side effects are minimal provided small doses are administered and the boy has regular blood tests early in the treatment to monitor serum testosterone levels.

Many myths exist as to adverse effects of long term testosterone use in adult males, but these have proved to be unfounded with good scientific research.

Prostate Disease

• Benign prostatic hyperplasia (BPH or enlarged prostate): The use of testosterone will increase the size of the prostate, mainly during the first six months of treatment. Men with testosterone deficiency often have reduced prostate size and most increases in prostate size result in a return to "normal" prostate volume. A number of medical studies have

failed to show any deterioration of obstructive symptoms attributable to benign prostatic hyperplasia during treatment and urinary retention has not been reported at rates higher than in control subjects. However, if the increased size of your prostate interferes with the flow of your urine, then you can have a TURP procedure (transurethral resection of the prostate gland) to "shell out" the overgrown prostate.

• Prostate cancer: The most important theoretical danger of testosterone treatment is to increase the risk of developing prostate cancer. Whilst lowering of testosterone levels is a standard treatment for metastatic prostate cancer, there is no available evidence to suggest that replacement of low testosterone levels into the normal range, leads to any increase in the occurrence of the disease. Numerous medical papers have shown that there was no significant increase in the occurrence of prostate cancer and a variable increase in the levels of prostate specific antigen (PSA). The PSA is often below normal in hypogonadal men and is generally restored to normal with testosterone supplementation. The authors of one paper concluded that "there is no compelling evidence that testosterone has a causative role in prostate cancer... (nor) increases the risk". Prior to and during the monitoring of testosterone replacement therapy, regular digital rectal examination and measurement of PSA are recommended.

Adverse Changes in Serum Lipids

Synthetic testosterone derivatives are associated with adverse changes in serum lipids (blood cholesterol and triglycerides). However, the use of pure testosterone (e.g., testosterone implants, patches, creams and gels) is not associated with any changes to cholesterol or serum lipid concentrations.

There is no known interaction between testosterone and lipid lowering medication like statins (e.g., Baycol®, Lipitor®, Mevacor®, and Zocor®).

Coronary Heart Disease

A major theoretical concern regarding testosterone administration is the possibility that it could increase the risk of cardio-vascular disease. Such a concept is based on the higher incidence of cardio vascular events in men compared to women. However, this may be much more readily explicable by the protective effects of estrogen in women. There is little

data to support a causal relationship between high testosterone levels and heart disease. In fact, a significant body of evidence suggests that the opposite may be true and that men with low testosterone levels may be at higher cardio-vascular risk. There are reports that testosterone replacement can improve symptoms of chronic stable angina and there are direct observations showing vasodilatation following intra-coronary injections of testosterone. There are no reports of increasing incidence of cardio-vascular disease, including myocardial infarction (MI), stroke (CVA) or angina, in reports of testosterone replacement therapy.

Polycythemia

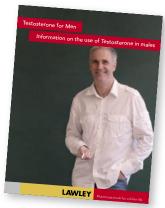
Polycythemia is an abnormal increase in red blood cells. It is a well know side effect of chronic testosterone administration, particularly using the intramuscular route (IM injections), where high serum testosterone levels are present for some days following each injection. Your doctor will check for polycythemia with a hematocrit blood test, which is the percentage of your whole blood that is composed of red blood cells, as opposed to blood serum. The normal hematocrit range for an adult male is 42% to 54%. It is noteworthy that men with hypogonadism tend to have anaemia (lack of red blood cells) and reduced hematocrit concentrations and testosterone replacement leads to normalization. There is a direct dose relationship between the testosterone dose and the incidence of polycythemia. This effect, while not life threatening or severe, requires regular, annual hematocrit monitoring by a medical professional during testosterone replacement therapy. The hematocrit test is performed as a part of the Complete or Full Blood Count, and your doctor may refer to it as a CBC or FBC.

Long term risks with testosterone replacement therapy are minimal, particularly in regard to the major concerns addressed above. Side-effects from excessive testosterone dosing are noted, but such adverse reactions are extremely unlikely with testosterone cream or gel topical administration, the most commonly used forms of testosterone.

For comprehensive information on the safe and effective use of testosterone in men see www.hormonesolutions.com.au or click on the link below.

Testosterone for Men Information Booklet [199 kb]

In women, as with men, testosterone plays a crucial role in sexual motivation (libido), energy levels, mood and bone metabolism. Women produce testosterone from the ovaries and adrenal glands. 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. For comprehensive information on the safe and effective use of testosterone in women see www.hormonesolutions.com.au or click on the link below.

Testosterone for Women Information Booklet [215 kb]



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 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.

Who should not use natural progesterone cream?

Do not use PRO-FEME® progesterone cream if you have:

- A known allergy or sensitivity to any of the ingredients in the cream, especially almond oil
- Yellow jaundice or liver disease
- Undiagnosed vaginal bleeding
- The immune disease herpes gestationis, which develops during pregnancy and is also called pemphigoid gestationis (PG)
- A clotting disorder, like deep vein thrombosis (DVT)
- Severe h sease
- A personal history of carcinoma (cancer) of the breast or endometrium

How do I use natural hormones creams?

The aim of hormone replacement therapy is to mimic your gonads' natural hormone production as much as possible. Lawley Pharmaceutical's applicators are marked in unit doses. You must tailor the strength and amount of cream you apply and the number of days you apply it to your individual requirements. Your doctor may alter the dose recommended in the directions on the product insert. Rub the correct amount on your abdomen, upper thigh, or scrotum (for men). Your doctor may instruct you to alternate different types of hormones or to use one continuously. Follow your doctor's instructions exactly.

Females. The aim of natural hormone replacement therapy is to mimic your body's normal natural hormone production as much as possible. PRO-FEME® dose applicators are marked in unit doses. You must tailor the strength, amount and the number of days you apply the cream to your individual requirements. Your doctor may alter the dose recommended in the directions on the product insert.

Women's hormonal cycles are more complex than the hormone profile of men. PRO-FEME® 3.2% progesterone cream is prescribed to control the symptoms of benign breast disorders during premenstrual syndrome (PMS), menopause, and the perimenopause.

The usual dose of PRO-FEME® 3.2% progesterone cream for treating menopausal symptoms is two units (32mg progesterone) used once daily

for three weeks continuously then cease for 1 week. Review symptoms using the Progesterone Deficiency Menopause Symptoms Assessment questionnaire at http://www.hormonesolutions.com.au/content/natural-progesterone-cream/menopause-self-assessment.php after 3 months of treatment.

In pre and perimenopausal women the usual dose of PRO-FEME® 3.2% progesterone cream is 2 units (32mg progesterone) applied daily from day 12 to 26 of the cycle.



PRO-FEME® Prescribing Information and Consumer Medicine Information can be downloaded from http://www.hormonesolutions.com.au (or by clicking on the hyperlinks).

PRO-FEME® can be an appropriate adjunct therapy for other progesterone-deficiency conditions, like surgical menopause from hysterectomy, ovarian cysts, uterine fibroids, estrogen-dependent malignancies, and fibrocystic breasts. If you have had a hysterectomy, the doctor may prescribe estrogen only for menopausal symptoms. This estrogen needs to be supported with natural progesterone to prevent possible estrogen dominance.

Boys and Men. Testosterone production increases when a boy enters puberty. Your doctor may choose ANDROMEN® 2% testosterone cream for a male youngster. Testosterone production tends to decrease around 50 years of age. A good testosterone target range for an adult man to maintain is 350 – 1,000 nanograms per deciliter (ng/dl) or 15-35 nmol/L of blood serum. In adult males applying 2 units (50mg) of ANDROMEN® FORTE 5% natural testosterone cream every morning to the scrotum can help maintain this target range. Allow the cream to absorb into the scrotal skin before dressing. Wash your hands well with soapy water after use. There are no reports of acute testosterone overdose in the literature; however, Andromen® Forte 5% testosterone cream is too strong for use by women and children.



ANDROMEN® and ANDROMEN® FORTE Prescribing Information and Consumer Medicine Information can be downloaded from http://www.hormonesolutions.com.au (or by clicking on the hyperlinks).

Which form of natural hormone treatment is best for me?

If one Googles "natural hormone cream" or "progesterone cream" or "testosterone cream" there are dozens of products claiming to be the "best" and "authentic" natural progesterone/testosterone creams or gel. 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 and its equipment, processes, and packaging. PRO-FEME® natural progesterone creams are guaranteed stable, effective, and potent. 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 are 70% pure. 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 because cosmetic products do not require clinical trials to prove their worth.
- 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 PRO-FEME® 3.2% and 10% progesterone cream for females, ANDROMEN® 2% and ANDROMEN® FORTE 5% testosterone cream for males and ANDRO-FEME® 1% testosterone cream for women.

PRO-FEME® 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, PRO-FEME® Progesterone creams for women are the world's only clinically trialled and tested pharmaceutical grade progesterone creams using natural bioidentical progesterone. PRO-FEME® progesterone creams are listed with the Australian government (AUST L 95334 / L 70886).

ANDROMEN®, ANDROMEN® FORTE AND ANDRO-FEME® 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 underproduction by the testes or ovaries and/or adrenal glands. Applied topically to the skin, ANDROMEN®, ANDROMEN® FORTE and ANDRO-FEME® are the world's only clinically trialled and tested pharmaceutical grade testosterone creams using natural bio-identical testosterone. ANDROMEN®, ANDROMEN® FORTE and ANDRO-FEME testosterone creams are listed with the Australian government (AUST L 70886 / AUST L 95334 and AUST L 70887 respectively).

What are my alternatives?

Boys and Men

Your doctor may suggest pulsatile LHRH or hCG injections as an alternative for a boy with hypogonadotropic hypogonadism to encourage his testicles to grow. This alternative treatment is more complex than testosterone replacement. Childhood testosterone treatment does not interfere with fertility treatment later on, so many patients prefer painless testosterone cream that delivers a steady daily dose. When the grown man wants to have a child, fertility may be induced with either pulsatile LHRH or a combination of hCG and FSH.

There are different methods of testing semen. Ensure your lab uses a GSA kit, because it is recommended by the World Health Organization as the gold standard for testing semen. A flow cytometer can check for 100 times more cells than a technician can manually, using a lighted microscope with a counting chamber. Using a GSA kit for semen analysis gives the lab better quality control because the cell count is more precise and the technician's skill and experience are less critical. It is easier to repeat the test with a flow cytometer than it is manually. Deviation between testing technicians is less with a flow cytometer than it is with the manual Routine Method.

Men with hypergonadotropic hypogonadism cannot produce a child. Consider adoption or a sperm donor. Women with primary hypogonadism are infertile, but can carry a pregnancy from a donor's egg to term.

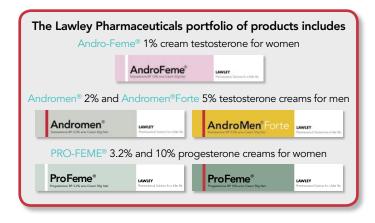
Women

In women your doctor may suggest birth control pills or synthetic estrogen and progestin for your daughter. Medroxyprogesterone is a cheap synthetic progestin that is similar to progesterone, but with a very narrow spectrum of action on the uterus and unlike progesterone has significant side effects. It is sold as Provera® and is commonly used to treat heavy menstrual bleeding. Medroxyprogesterone acetate causes birth defects if the girl accidentally becomes pregnant. It passes into breast milk and damages the infant, so it is not suitable for postnatal depression. Medroxyprogesterone increases the risk of blood clots, especially if your daughter smokes. It 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. The minor side effects of synthetic medroxyprogesterone acetate are weight gain, itchy skin rash, acne, hair loss, insomnia, bloating, menstrual irregularities, vaginal discharge and tender breasts.

About Lawley Pharmaceuticals

Lawley Pharmaceuticals 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. As the principal of Lawley Pharmaceuticals, Mr. Buckley has presided over the development, research, clinical trial program, regulatory process, development and marketing of the company.



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, evidence-based medical research, naturally occurring hormones as cornerstone treatments for diseases such as breast cancer, infertility, hypogonadism, post natal 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

- The effectiveness of transdermal progesterone cream on menopausal symptoms, lipids and bone markers
- The effects of sequential transdermal progesterone cream on endometrium bleeding pattern and salivary levels in post-menopausal women
- Evaluation of serum progesterone levels after topical applications of Andro-Feme® cream in post menopausal women with symptoms of progesterone deficiency
- Systemic absorption after transdermal application of labelled progesterone in rats
- Plasma and saliva concentrations of progesterone in pre- and postmenopausal women after topical application of progesterone cream
- The effect of progesterone replacement therapy on sexuality, mood and cognition of post-menopausal women
- Long-Term pharmacokinetics and clinical efficacy of Andromen[®]Forte
 cream for androgen replacement in hypogonadal women.
- 8. Transdermal progesterone therapy improves well-being, mood, and sexual function in premenopausal women.
- The pharmacokinetics of Andro-Feme®1% progesterone cream following two week, once daily application in progesterone deficient women.

Where can I find out more?

- 1. www.hypogonadism.biz
- 2. www.childhoodhypogonadism.com
- www.hormonesolutions.com.au
- 4. Andrology Australia http://www.andrologyaustralia.org
- 5. Hyster Sisters http://www.hystersisters.com/vb2/article_97232.htm
- Medline for progesterone http://www.nlm.nih.gov/medlineplus/ druginfo/medmaster/a604017.html
- Medline for testosterone http://www.nlm.nih.gov/medlineplus/ tutorials/lowtestosterone/htm/index.htm
- 8. National Human Genome Research Institute http://www.genome.gov/
- Knowledge, Support & Action http://www.genetic.org/knowledge/ support/action/257
- Teens Health http://kidshealth.org/teen/sexual_health/changing_ body/delayed_puberty.html
- Dr. John Maher on progesterone http://www.bio.net/bionet/mm/ ageing/2001-March/004369.html

References for Medical Professionals

- www.DoctorDirect.com.au, or call 1-800 62 506 or 08 9228 9033 US and Canadians call tollfree 1-800-961-7813 to speak with a pharmacist, or e-mail info@lawleypharm.com.au.
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 J Appl Genet. 2008;49(3):301-303.

Glossary

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

Alfa-fetoprotein (AFP): A tumor marker for certain cancers of the testes and ovaries. Adults should have less than 15 nanograms of alfa-fetoprotein per milliliter of blood.

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).

Azoospermia: The ejaculate contains no sperm at all.

BhCG: Females excrete this pregnancy hormone 10 days after conception. Doctors use it 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. If you had a hysterectomy (removal of the uterus) or orchiectomy (removal of the testicles) but are still excreting Beta HCG, then there is residual cancer that must be removed. Males with carcinoma of the testicles excrete this hormone. Normal males never excrete Beta HCG.

CA-15-3: Cancer Antigen 15-3, which is elevated in 3/4 of patients with metastatic breast cancer.

CA-125: Cancer Antigen 125 is a tumor marker for ovarian cancer.

CA-549: Cancer Antigen 549 is elevated in half of patients with advanced breast cancer.

Cryptorchidism: Undescended testicles. One or both testes stay in the abdominal cavity as they are before birth, instead of entering the scrotum. The doctor can try to manipulate the testes down into the scrotum, or can move them surgically if manipulation fails. It is dangerous to leave the testes in the abdomen, as it increases the risk of testicular cancer. The testes need to be kept cool in the scrotum to produce sperm. The intense core heat of the abdomen kills sperm.

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

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

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

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

Fibrosis: Scar tissue replaces healthy tissue because of degeneration, injury, or infection.

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

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

Gynecomastia: Enlargement of one or both male breasts, sometimes with milk production. (This is not pubertal hypertrophy, where a tender disc of enlarged tissue forms under the boy's nipple and disappears within a year.) Causes of gynecomastia include: Klinefelter syndrome; hormone imbalance; weight gain; taking steroids or estrogen; cirrhosis of the liver; tumor in the testicles, breast, or lung. Gynecomastia should always be evaluated by a doctor.

Hyalinized: Healthy tissue is replaced by hyaline (clear or translucent white, glassy collagen fibers) due to degeneration.

Hypospadias: A birth defect where the boy's urethra opens onto the underside of the penis or below it, instead of the end of the glans.

Hypothalamus: The section of the brain that regulates body temperature, chemical balance, the pituitary gland, and the autonomic nervous system. The hypothalamus is part of the limbic system, so it regulates sexual appetite, eating, sleep, and emotions. It influences heart and breathing rates and blood pressure. The hypothalamus is located in the grey matter, below the thalamus, in the center of the brain. The pituitary gland hangs on a stalk below the hypothalamus.

Karyotype: Number, form, and size of chromosomes.

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

Oligospermia: The ejaculate contains fewer sperm than normal.

Phenotype: The physical characteristics of the boy comprised of his genetic makeup and his environment.

Pituitary gland: Connected to the hypothalamus, the pituitary controls growth hormone, prolactin for milk production, and follicle-stimulating hormone (FSH) to stimulate ovaries. The pituitary stimulates the adrenal glands and the thyroid.

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.

Seminiferous tubules: Two or three convoluted tubes in the testicles, where sperm are made.

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.

USA specialist Dr. John E. Morley, M.B., B. Ch. developed this questionnaire to aid your physician in diagnosing androgen deficiency.

A more comprehensive Self-Assessment of Ageing Male Symptoms is the AMS Questionnaire. This Ageing Males' Symptoms (AMS) questionnaire is a modified version adapted from Lunenfeld B, Gooren L, eds. Textbook of Mens' Health. London: Parthenon Publishing, 2002:34.

The Ageing Male Symptoms (AMS) Questionnaire can be taken online by clicking on the above link or the image below.

Men, bring this survey to your doctor.								
Che	ck 'yes' or 'no'	YES	NO					
1	Do you have a decrease in libido (sex drive)?							
2	Do you have a lack of energy?							
3	Do you have a decrease in strength or endurance?							
4	Have you lost height?							
5	Have you noticed a decreased "enjoyment of life"?							
6	Are you sad and/or grumpy?							
7	Are your erections less strong?							
8	Have you noticed a recent deterioration in your ability to play sports?							
9	Are you falling asleep after dinner?							
10	Has there been a recent deterioration in your work performance?							



Women, bring this survey to your doctor.

SYMPTOM TRACKER – Check off your symptoms √ for Dates: to														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Period = P														
Acne														
Anxious/Depressed														
Appetite Change														
Backache														
Bloating														
Breasts Tender														
Can't Concentrate														
Constipation														
Cramps														
Diarrhea														
Disturbed Sleep														
Food Craving														
Headache														
Joint/Muscle Pain														
Moody/Crying														
Poor Memory														
Tense/Irritable														
Tired														
Other														

Women, bring this survey to your doctor.

SYMPTOM TRACKER – Check off your symptoms v for Dates:														
Day	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Period = P														
Acne														
Anxious/Depressed														
Appetite Change														
Backache														
Bloating														
Breasts Tender														
Can't Concentrate														
Constipation														
Cramps														
Diarrhea														
Disturbed Sleep														
Food Craving														
Headache														
Joint/Muscle Pain														
Moody/Crying														
Poor Memory														
Tense/Irritable														
Tired														
Other														

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