

Understanding Gynecomastia

(Male Breast Development)



Natural Testosterone Cream

LAWLEY PHARMACEUTICALS FOR A FULLER LIFE

Information for men on the safe and effective use of the hormone testosterone
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What is gynecomastia?

Gynecomastia is abnormally large breast development in a male due to swelling of the mammary gland. It can involve only one breast or both. The rate of breast development is often uneven, so the breasts may be different sizes. Breast enlargement may be accompanied by breast pain (mastalgia). True gynecomastia is caused by a hormonal imbalance. The affected male produces too much estradiol, the female breast growth hormone. Pseudogynecomastia is breast enlargement caused by fat deposition over the entire chest, not localized to the breasts.

Newborn and pubescent boys often develop temporary breast enlargement.

Why does gynecomastia develop?

Breast development usually occurs in males because of excessive female hormone stimulation. It can also occur because of:

- Testosterone deficiency
- Workplace exposure to estrogen
- Genetic disorders like Klinefelter, Wilson-Turner, & Reifenstein syndromes
- Goiter (overactive thyroid gland or thyrotoxicosis)
- Chronic kidney failure
- Hemodialysis
- Cirrhosis of the liver
- Hemochromatosis (excess iron)
- Adrenal gland disease
- Body-building through anabolic steroids
- Regular use of alcohol, cannabis (marijuana) or heroin
- Tumors of the brain, lungs, testicles, adrenal glands or breast
- Androgen insensitivity syndrome
- Hermaphroditism (ambiguous male/female genitals)
- Recovery from malnutrition (refeeding gynecomastia, Obal syndrome)
- Testicular failure following mumps
- Cancer chemotherapy (estramustine)
- Radiation therapy for cancer of the testicles
- Prescription drugs (digitalis, tricyclic antidepressants, cardiac glycosides, antihypertensives, spironolactone, cimetidine, ketoconazole, β hCG, phenothiazines, and flutamide)
- Enzyme deficiency (17-beta-hydroxysteroid dehydrogenase isozyme 3 or aromatase)
- Retinitis pigmentosa

In addition to the 21 most frequent causes of gynecomastia listed above, there are a host of very rare diseases that list it as a sign. They are too numerous to list here.

Essentially, an imbalance occurs between estrogens (female hormones) and androgens (male hormones). Milk ducts in the breasts are stimulated to grow by estrogens, growth hormone (GH) and corticosteroids. Subsequently, the areolar lobules fill with milk when they are stimulated by prolactin and progesterone.

Who develops gynecomastia?

The most likely males to develop gynecomastia are newborns, pubescent boys, and elderly men because their hormones are in transition. Between 60% and 90% of newborn boys develop temporary gynecomastia because of exposure to their mothers' estrogen hormone.

About 65% of adolescent boys experience transient gynecomastia as a normal part of puberty. The peak time is 14 to 14.5 years of age.

About 15% of adult men worldwide have gynecomastia.

Two-thirds of affected men have bilateral (on both sides) gynecomastia. One-third of affected men have unilateral (one-sided) gynecomastia.

Here are rough estimates for the prevalence of gynecomastia in countries where the predominant language is English:

COUNTRY	ESTIMATED NUMBER OF AFFECTED MEN
Australia	1,098,15
United Kingdom	3,323,752
United States	16,194,231
Canada	1,792,713
New Zealand	220,247
South Africa	2,451,202

The incidence of gynecomastia is greater in males with a genetic disorder affecting their sex chromosomes. For example, 1 in 650 males in Australia is born with Klinefelter syndrome, and is prone to gynecomastia. In the U.S.A., 1 in 500 to 1,000 males has an extra sex chromosome.

Ancient Egyptian statues of men with gynecomastia were unearthed by archaeologists, so we know it has always been with us. Mastectomy (breast reduction surgery for gynecomastia) was reported in 690 A.D. by Paulas and Aegina.

What are the signs and symptoms of gynecomastia?

True gynecomastia initially shows up as a small, tender lump below the nipple, about the size of a marble. The left breast is more likely to be affected. The areola (coloured area around the nipple) swells next. A small amount of milk flow (galactorrhea) often occurs spontaneously. The slang term is "witch's milk". This will probably resolve in your infant son by the end of his second week of life, but may last until he is 2 years old.

Most boys develop physiologic gynecomastia, also called pubertal hypertrophy, when they reach puberty, around age 14. However, gynecomastia may occur as early as 10 years of age. It is usually tender and uneven (asymmetrical). It will likely resolve in a few months to two years. Very seldom will it last until the adolescent turns 20. In serious cases where both mammary glands and fat are involved, the breast can grow up to a D cup size. About 15% of pubescent gynecomastia lingers into adulthood.

Gynecomastia may develop again or for the first time when the man reaches 60, usually due to testosterone deficiency, prescription drug use, or a tumor. Water retention (edema), testicular shrinkage (atrophy) and lack of sex drive (libido) may co-occur with the gynecomastia, as a result of increased estrogen.

Breast cancer accounts for only 0.7% of all malignancies in men. Breast cancer usually occurs only in one breast, not both. A malignant breast tumor usually is not centered under the areola, as gynecomastia is. A malignant breast tumor usually sits off to one side (eccentricity).

The only well-established correlation between gynecomastia and breast cancer is in men with Klinefelter syndrome, who have a 50% increase in their chances of developing breast cancer.

How is gynecomastia classified?

If your gynecomastia has lasted less than four months, then it probably is florid type, meaning the milk ducts increased in number and length, followed by swelling. The breast increased its vascularity and pseudolobules formed.

If your gynecomastia has lasted four to 12 months, then it is probably fibrous type, meaning only the ducts dilated, without the swelling and fatty deposits.

Your gynecomastia could also be intermediate type, which is a combination of florid and fibrous involvement.

Testosterone treatment in the early stages in gynecomastia often helps to reduce breast growth.

The three classifications of gynecomastia for surgical purposes are:

- 1. Glandular** – An overgrowth of mammary gland tissue occurs. Glandular gynecomastia always requires surgical removal.
- 2. Fatty Glandular** – An overgrowth of both mammary gland tissue and fatty deposits co-occur. Treatment involves breast reduction surgery and liposuction to contour the chest.
- 3. Simple Fatty** – An overgrowth of fat only, with minimal growth of fibrous breast tissue. Treatment is liposuction.

What are my treatment options?

First aid for mastalgia (breast pain) is to apply cold compresses and use analgesics. Place ice in a plastic bag and wrap it in a towel. Never allow ice to rest directly on the breast, because frostbite can occur. Hold the cold compress gently over the breast for a maximum of 20 minutes. Allow the breast at least 20 minutes to recover from the chilling. Never use aspirin (acetylsalicylic acid or ASA) for a child under 19 who has a fever of viral origin. Children can develop Reyes syndrome, a rare but deadly form of brain and liver damage, from aspirin exposure. A better alternative is acetaminophen (paracetamol).

Self-help measures to reduce pain include:

1. Avoid caffeine
2. Take evening primrose oil and Vitamin E

If the breast swelling does not resolve in two weeks, see your doctor.

Most cases of gynecomastia in children do not require treatment. Your doctor will probably adopt a “watchful waiting” approach for one or two years.

True gynecomastia may respond to a prescription for testosterone, tamoxifen, clomiphene, danazol, oral contraceptives, bromocriptine, GnRH agonists, or testolactone. Pseudogynecomastia from obesity just requires diet and exercise, although obesity is often associated with lowered testosterone levels, therefore serum testosterone should be tested. If a painful cyst forms, your doctor may aspirate the fluid from it with a syringe to relieve pressure.

If drug treatment is unsuccessful after one year, then your doctor may suggest breast irradiation therapy. If that is unsuccessful, your doctor may suggest breast reduction surgery (mastectomy) with or without liposuction.

How is breast reduction performed?

You must stop smoking two weeks before surgery. You cannot take Vitamin E, herbs, aspirin, and anti-inflammatories for two weeks before the surgery because they increase bleeding.

Generally, men who desire breast reduction (mastectomy) book surgery with a qualified plastic surgeon or a general surgeon on an out-patient basis. If you have pre-existing medical conditions, then an in-patient stay will be required. Most men opt for general anesthetic (complete unconsciousness), but sedation with a local anesthetic can also be used. It takes about 60 to 90 minutes per side. Usually, a surgeon will not consider you for mastectomy until you have finished puberty (reached 18 to 20 years old).

Many health insurance plans do not provide gynecomastia reduction coverage because it is considered cosmetic surgery. The price for gynecomastia reduction surgery ranges from \$5,000 in Australia up to \$7,500 in the U.S.A.

Mastectomy involves removal of breast glandular tissue with a scalpel. The surgeon makes a 1 centimeter incision as inconspicuously as possible, either in the armpit or through the areola. The surgeon shells out glandular tissue and fat from the sides of the breast, beneath the areola, and the base of the breast.

Surgeons tailor the incision to your particular case. A Webster incision is a half-circle through the areola. A transverse incision cuts right across the areola and nipple. The triple-V incision exposes a great deal of tissue when the overgrowth is advanced. If your nipple needs to be removed and repositioned, the surgeon uses a Letterman technique to fold the nipple back as a flap. If you have massive breasts, the surgeon makes an elliptical incision around the entire breast.

Liposuction may be necessary to contour the remaining fat.

The liposuction tubing (cannula) is inserted through the same incisions made by the scalpel. Liposuction requires salt water (saline) and anesthetic to be injected into your breast (tumescence). The surgeon inserts an ultrasonic probe into the breast to liquefy fat and glandular tissue. The slurry is vacuumed out at high speed.

Skin removal may be necessary if the breasts were very large, to prevent sagging after the procedure. The red, raised scars will gradually fade and flatten over the next six months. Wear a silicone sheet over the scar for two months and avoid sun exposure for six months so the scar will not become darkly pigmented.

Your nurse will encourage you to get up and walk soon after the surgery to prevent pooling of body fluids and pneumonia. You can take a shower two days after your surgery. Barring complications, you probably can return to work in two days, but book the week off work as a precaution. You must return to have your surgeon remove your sutures in one or two weeks. Most men can resume exercising in three weeks.

Mastectomy always produces bruising, swelling and scarring to some degree. Hence, you may be disappointed if you expected an immediate flattening of your chest. Your chest may be numbed or you may have diminished sensation for up to a year because nerves are severed.

You must wear absorbent dressings for the first 24 hours after surgery, because your wounds will drain a combination of blood, liquefied fat, and

injection fluid. Expect to bandage your wounds for two weeks thereafter. You will be required to wear an elastic pressure bandage or surgical garment for six weeks. You must wear it day and night for two weeks to reduce swelling and help prevent skin sagging. Then for the next four weeks, just wear it at night. Massage the area daily to prevent contour irregularities from developing. You will not know the final outcome of the procedure for three months to one year, as your chest reshapes itself. You will require follow-up examinations once per month for six consecutive months.

Every surgery entails risk. Possible complications of mastectomy include:

- Adverse reaction to the anesthetic
- Bleeding
- Infection
- Sloughed skin or nipple death (necrosis)
- Inverted nipple
- Fluid pocket formation
- Uneven pigmentation
- Noticeable asymmetry requiring a second procedure to correct it

If you are very obese, or use alcohol, anabolic steroids, or marijuana, then you are not a good candidate for surgery. The surgical team will most likely decline to perform the mastectomy until you lose weight and/or stop taking drugs. Gynecomastia improves spontaneously in 60% of men who stop taking the aggravating drugs.

If you have a pre-existing medical condition that contributed to the gynecomastia, such as diabetes, liver, heart, or lung disease, then you are not a good candidate for surgery. Your doctor will likely recommend conservative treatment because the benefits of surgery do not outweigh the risks.

What are the pros and cons of mastectomy?

Mastectomy is the traditional treatment for long-standing, neglected gynecomastia. It removes many breast and fat cells, so the contour improvement is permanent. If you regain a lot of weight, the remaining cells will grow again, but probably not to the same extent. If you do not have the underlying condition treated, the breast tissue will definitely grow back.

What are the pros and cons of testosterone treatment?

The hormone testosterone can produce a dramatic improvement in cases of testosterone deficiency of recent onset. Men with testicular failure, viral orchitis, and anorchia experience remission of symptoms including gynecomastia very quickly with testosterone replacement therapy (TRT). Treatment with testosterone is painless and private. You do not need to explain your absence from work to your employer or insurance company. You do not require a change in assignment to light duties during your recovery. Men with Klinefelter syndrome may have inconsistent results despite using testosterone. Patients with liver disease may see an increase in their blood estrogen levels.

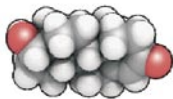
What is the role of testosterone in humans?

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 their ovaries than males do in their testicles.

The small amount of testosterone present in females does not have a masculinizing effect on them.

Testosterone increases libido and affects mood in both sexes.

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.



Testosterone molecule,
D. Dinneen, July 2008

What are the side-effects of testosterone replacement therapy?

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.

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 in 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". 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 cardiovascular 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 cardiovascular disease, including myocardial infarction (MI), stroke (CVA) or angina, in reports of testosterone replacement therapy.

Polycythemia (an abnormal increase in red blood cells)

A well know side effect of chronic testosterone administration, particularly using the intramuscular route (injections), where high serum testosterone levels are present for some days following each injection, is the occurrence of polycythemia, with a rise in hematocrit (the percent of whole blood that is composed of red blood cells). It is noteworthy that men with hypogonadism tend to have anaemia 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 the need for regular monitoring (yearly) by a medical professional of this parameter during testosterone replacement therapy.

Lowering Testosterone

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

You can marginally increase your testosterone level with exercise. However, 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 much carbohydrate and too little fat, it can deplete testosterone.

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.

Other Benefits of Testosterone

Testosterone is the primary hormone responsible for sexual function, sexual motivation, sexual arousal and fantasy in men of all ages.

Cancer patients who have had their testicles removed or suffered permanent and irreversible testicular damage due to chemotherapy or radiotherapy may use testosterone to compensate for the loss.

Testosterone supplementation helps cancer survivors immensely, but it also benefits people with other conditions:

- Boys with genetic disorders that cause a delay in puberty, like Klinefelter syndrome
- Testosterone is responsible for maintaining muscle mass and muscle strength in athletes
- AIDS patients often use testosterone to curtail unwanted weight loss and muscle wasting (cachexia)
- Testosterone plays a pivotal role in bone metabolism, especially for older men who take prednisone, a steroid anti-inflammatory.
- Testosterone slows bone loss and builds replacement bone.
- Testosterone exerts a strong influence on mood, energy levels, and concentration
- Androgen Deficient Ageing Males (ADAM) or late-onset hypogonadal males apply natural testosterone cream and gels to combat their:
 - Mood changes (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 (lipodystrophy)
 - Rudimentary breast development (man-boobs or gynecomastia)
 - Low sperm in the semen

Take the online [Ageing Male Symptoms Self Assessment Test](#)

Women take reduced-dose testosterone to treat poor libido. This is a common “off-label” practice among doctors in the USA, where no testosterone product is officially approved for use by women. The situation in Australia is distinctly different. Lawley Pharmaceuticals produces a

1% testosterone cream ([Andro-Feme®](#)), tailored especially for women. Andro-Feme® is a popular testosterone treatment option for use in women because it involves no surgery, no pain, is applied by the woman in the privacy of her own home, and the dose is accurately controlled.

What about homeopathic treatment?

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 testosterone, nor have they been demonstrated to cause any change in testosterone levels. Testosterone is the worldwide gold standard for restoring male secondary sexual characteristics and treating androgen deficiency.

Who should not take testosterone?

Do not take testosterone replacement therapy (TRT) if you are a man with any of these pre-existing conditions:

- Known hypersensitivity or allergy to testosterone
- Existing or suspected cancer of the breast or prostate gland
- Severe heart, kidney, or liver disease
- Excessive calcium in the blood (hypercalcemia)

If you are a woman, you cannot take testosterone during pregnancy to avoid giving birth to a son with Klinefelter syndrome or another genetic disorder. The genetic problem already occurred when the cells divided and is irreversible. Do not take testosterone while you are breastfeeding, as it will adversely affect your child through the milk. The benefits do not outweigh the risks.

What precautions should I take?

Ask your doctor to order a blood test for testosterone. The normal range is 300 to 1,200 ng/dl or 10 to 35 nmol/L. It will be highest in the morning. Target your hormone treatment to achieve this same optimum level.

Ask for a copy of all your reports: Ultrasound, imaging, laboratory blood work, and pathology.

See an endocrinologist – a hormone specialist – before you make an appointment with a surgeon.

Before initiating TRT, your doctor should check for prostate abnormalities by means of a digital rectal examination (insertion of a gloved finger through the anus and feeling the hardness of the prostate gland) and a blood test for Prostate Specific Antigen (PSA). This is to ensure that you do not have prostate cancer and that complications of the prostate should not arise due to testosterone usage. Testosterone should not be used if there is prostate cancer or irregularities. During therapy, get a yearly PSA test for early detection of prostate cancer and a rectal examination of the prostate. You need regular hemoglobin, hematocrit, liver function, and cholesterol tests and frequent monitoring by your doctor for the risks discussed above.

If you have chronic liver or kidney disease, then you should only use testosterone under strict medical supervision.

What are the side-effects of testosterone replacement therapy?

Side-effects can occur if testosterone is used in excessive quantities. These may include:

- Too frequent or persistent erections (priapism)
- Nausea and vomiting
- Swelling of the ankles
- Acne
- Headache
- Gynecomastia (breast development) due to conversion to estrogen
- Increased appetite

These effects are usually associated with excessive levels of serum testosterone due to incorrect dose. Due to their mode of administration, testosterone gels and creams generally keep testosterone blood levels within the normal therapeutic range for men and therefore side effects are unlikely to occur. Spikes and troughs of testosterone are more likely to occur with injections.

Which testosterone route is best for me?

If one Googles “natural testosterone cream” or “testosterone gel” there are dozens of products claiming to be the “best” and “authentic” natural testosterone creams or gel. Just how does a man determine which product is most suited to his requirements? The following is an outline of basic manufacturing processes to help you decide. The three quality standards of natural testosterone 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. Andromen® and Andromen® Forte natural testosterone 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 testosterone creams for men available worldwide are Andromen® 2% and Andromen® Forte 5% cream from Lawley Pharmaceuticals, Australia.



Andromen® 2% and Andromen® Forte 5% testosterone creams are specifically targeted for use in men with declined or lowered serum testosterone levels due to genetic disorders, surgical or chemical interventions or ageing. Low testosterone in men is associated with declined libido, diminished sexual function, fatigue, lethargy, loss of motivation, decreased muscle mass and strength, depression, irritability and mood changes.

Applied topically to the skin, Andromen® Forte and Andromen® testosterone creams for men are the world's only clinically trialed and tested pharmaceutical grade testosterone creams using natural bio-identical testosterone. Andromen® Forte and Andromen® Testosterone Creams are listed with the Australian government (AUST L 95334 / L 70886). Andromen® [Prescribing Information](#) and [Consumer Medicine Information](#) can be downloaded from <http://www.hormonesolutions.com.au> (or by clicking on the link).

What can we expect when we visit the doctor?

Bring all prescription drugs, herbs, and supplements you are taking with you to your doctor's visit. Be honest with your doctor if you drink heavily or use street drugs. Your doctor may consult with a pharmacist to find out if your gynecomastia could be the result of a drug interaction.

Be prepared to answer these questions when the doctor takes your history:

- When did you first notice the breast enlargement?
- Is there any discharge, and if so, what color and consistency?

- Have you ever had mumps?
- Have you lost any hair on your chest, underarms or face?
- Do you also have enlarged testicles?
- Does your scrotum feel heavier than usual?
- Does your breast size vary or remain the same?
- Is there tenderness or pain in your breasts or groin?
- Have you ever had your nipples pierced, and if so, were there complications?
- Do you regularly use prescription or street drugs?
- Do you regularly drink alcohol?
- Do you use herbs or body building preparations?
- Have you noticed a decline in your sexual interest (libido)?
- Are you able to maintain an erection?
- Have you noticed any purple stretch marks on your skin, or facial swelling?
- Have you ever had cyclical bleeding from your urinary tract?
- Have you ever had a urinary tract infection?
- Have you been fasting or unable to take regular nourishment until recently?

If you have bronze skin, it may flag your doctor to ask in-depth questions about your liver and kidney function.

Following the history, your doctor will then perform a physical examination of your breasts, sex organs, and neurological functioning. He or she will specifically look for dimpling, ulcers, color changes, and asymmetry in your breasts. Your doctor will feel (palpate) for a mass in your testicles because Leydig's and Sertoli's cell tumors cause gynecomastia. Your doctor must look at your groin for ambiguous genitals (pseudohermaphroditism and testicular feminization). Many nerve conditions are associated with gynecomastia, so your doctor must test your reflexes and muscle strength.

Diagnosics

A diagnosis is when your doctor names your disease. Preliminary diagnostic tests help your doctor to narrow down the diagnosis, but confirmatory tests are usually required. For example, if your hormone blood tests suggest Klinefelter syndrome, then your doctor swabs the

inside of your cheeks (buccal smear for Barr bodies) to confirm it.

A routine urine drug test is required as a standard legal precaution before treatment. You probably will be sent to the Diagnostic Imaging Department for chest and skull x-rays, a mammogram, and an ultrasound of your testicles. You may be asked to get a CT, MRI or PET scan, or a biopsy.

The usual preliminary blood tests for gynecomastia include:

PROFILE	TEST	NORMAL ADULT – MALE VALUE
Thyroid	T3	110 to 230 ng/dL
	T4	5 to 10 µg/dL
	TSH	1 to 4 µU/mL
Liver	AST	5 to 40 IU/L
	ALT	5 to 35 IU/L
	ALP	30 to 85 IU/mL
	Bilirubin	0.1 to 1.0 mg/dL
	Iron	60 to 190 µg/dL
	TIBC	250 to 420 µg/dL
Kidney	Creatinine	0.57 to 1.00 mg/dL
	BUN	7 to 20 mg/dL
Adrenals	Cortisol	4.3 to 22.4 µg/dL
	ACTH	6 to 48 pg/mL
Hormones	GH	0 to 8 ng/mL
	FSH	1.4 to 18.1 mIU/mL
	LH	1.5 to 9.3 mIU/mL
	HCG	0 mIU/mL
	Testosterone	500 to 1200 ng/dL
	Estradiol	<54 pg/mL
	Prolactin	< 20 ng/mL

These are guidelines only. Children and women have different normal values. Your laboratory adjusts its normal values for the local population it serves. It may use different units of measure. To find out more about diagnostic tests, visit Lab Tests Online: <http://www.labtestsonline.org/understanding/index.html>.

Differential Diagnosis

Your doctor will suspect **breast cancer** if there is: Breast growth on one side only (unilateral); nipple inversion or flattening; discharge that is not milk (watery, bloody, or pus-streaked); "orange peel" skin; heat or redness; an itching or burning sensation.

Your doctor will suspect **lung cancer** if you have: Breast growth on both sides; weight and appetite loss; chronic cough; bloody sputum; fatigue; wheezing; difficulty breathing (dyspnea); diffuse chest pain; and clubbed fingertips.

Your doctor will suspect a **brain tumor** of the pituitary gland if you have: Both breasts enlarged and producing milk; impotence; enlarged hands, feet, and jaw (prognathism); high blood pressure; sweating and heat intolerance; thick, oily, dark skin; burning and weakness in the limbs; blurred or double vision; headache; unexplained weight gain; a very deep voice.

Your doctor will suspect a **genetic disorder** if you have: Breast growth on both sides; very small sex organs; little or no beard; impotence; little interest in sex; below average IQ; a urethra that opens on the bottom of your penis, instead of the glans tip (hypospadias); ambiguous sexual organs; a history of cyclical bleeding through your urinary tract.

Your doctor will suspect a **tumor in your testicles** (choriocarcinoma or Leydig's cell tumor) if you have: Breast growth on both sides; sore nipples; low libido; painless swelling in the testis; a heavy sensation in the scrotum with a hard mass.

If you are a hemodialysis patient, your gynecomastia is part of end-stage renal disease (ESRD), which can only be cured by a kidney transplant.

Your doctor will investigate you for **kidney failure** if you have a: History of urinary tract infections; bronzed skin; high blood pressure; nausea and vomiting; alternating diarrhea and constipation; ammonia breath; scanty

urine; tiredness; mental fog; muscle cramps; bleed or bruise easily; no pain sensation in your toes and fingers; and a light salting (uremic frost) on your skin.

Your doctor will suspect Cushing syndrome, a disorder of the **adrenal glands**, or **cirrhosis of the liver** if you have: Breast growth on both sides (bilateral); weight gain about the torso only; impotence; low libido; shrunken testes; minimal beard growth; and body hair loss. Cirrhosis usually causes additional symptoms, like: Jaundice; severe pain in your upper right abdomen; spider veins; reddened palms; foul breath; swollen liver and abdomen (ascites); swollen limbs (edema); fever; muscle wasting; psychological changes; and slow clotting. Your doctor orders a urine sample for estrogen and 17-ketosteroids to rule out a feminizing adrenal tumor.

Your doctor will suspect a problem with the **thyroid** gland in your neck if it is swollen and you have: Bulging eyes; unexplained weight loss; increased hunger; diarrhea; tremors, nervousness, and irritability; racing heartbeat (tachycardia); sweating; low libido; impotence.

If you are an AIDS patient or had another wasting illness (cachexia) where you were **malnourished** and are now eating solids again, you may develop temporary gynecomastia that will resolve spontaneously as your body regains its vigor.

What is the treatment for gynecomastia?

Buy a breast binder (male brassiere, bro, or gynecomastia vest) while you are waiting for your treatment to take effect. The binder will flatten and support the sagging breast tissue and make your breast growth less obvious. www.figleaves.com is one mail order supplier.

Your doctor must treat the underlying reason for your gynecomastia. For example, you may require cancer chemotherapy or radioactive iodine for goiter. Expect to make lifestyle changes, like stopping anabolic steroids or marijuana use. You will likely need tamoxifen to combat your estrogen increase, or testolactone to inhibit your testosterone from being converted to estrogen, but these drugs alone will not cure it. If you have low self-esteem because of poor body image, psychotherapy and group

counseling can help. You will require additional treatment tailored to your specific case. If drug therapy is unsuccessful in reducing the size of your breasts, your doctor will offer breast reduction surgery as a last resort.

If you or your son have a genetic disorder, have been castrated, or the testicles have failed, then you will require testosterone replacement therapy (TRT).

When your son is 11 or 12 years old, the doctor will commence testosterone supplementation. Testosterone treatment options include injections, gels and scrotal cream. Common testosterone injections options include:

DRUG NAME	TRADE NAME
Testosterone enanthate	Delatestryl® Primoteston® Depot
Testosterone esters	Sustanon®
Testosterone cyprionate	Depo-Testosterone
Testosterone undecionate (slow release)	Reandron®, Nebido® Not available in the USA

Testosterone injection treatment (using short-acting injections) usually begins with a 50 mg dose on a monthly basis.

In teenagers the doctor will closely monitor your son's growth and the development of male secondary sex characteristics. Your son will need to have blood drawn to check his gonadotropin hormone levels.

In years past, adult males with Klinefelter syndrome and other genetic disorders that produce testosterone deficiency visited the doctor every two or three weeks to receive an intramuscular injection of 200 to 250 milligrams of testosterone enanthate, esters or cyprionate or at 6-monthly intervals for 600 to 1,000 milligrams testosterone implants.

More recently, testosterone gels (AndroGel®, Testogel® and Testim®) and testosterone creams (Andromen® and Andromen® Forte) have allowed patients to self-administer their testosterone requirements. Testosterone gels are applied to the abdomen, chest, shoulders and arms. Because testosterone gels are alcohol-based they cannot be applied scrotally, due to the sensitivity of scrotal skin.

Andromen®2% and Andromen® Forte 5% scrotal testosterone creams are the most recent and user friendly advance in testosterone administration. Scrotal skin is significantly more receptive to testosterone absorption due to its high blood flow, thin skin and low fat content. Testosterone cream applied to the scrotum achieves significantly higher testosterone blood levels than the equivalent amount of testosterone applied to other areas of the body. This represents significant cost savings to patients.

Unlike intramuscular injections and implants, the cream is painless. The daily dose you receive with cream is even. Injections produce uneven testosterone blood levels because they wear off and have to be replenished every 7 to 22 days.

Testosterone production increases when a boy enters puberty. Testosterone production decreases when a man turns 50. A good testosterone target range for an adult Klinefelter man to maintain is 300 to 1,000 nanograms per deciliter (ng/dl) of blood serum (or 10.5 to 35 nmol/L). Applying 1 gram (50 mg testosterone) of Andromen® Forte 5% natural testosterone cream every night to your scrotum will help maintain this target range. Allow the cream to absorb into the skin before dressing. Wash your hands well with soapy water after use.

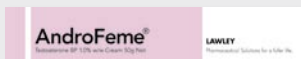
About Lawley Pharmaceuticals

Lawley Pharmaceuticals is a privately owned pharmaceutical company which focuses on the transdermal administration of the naturally occurring hormones testosterone, progesterone 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.

The Lawley Pharmaceuticals portfolio of products includes

AndroFeme® 1% cream testosterone for women



Andromen® 2% and Andromen®Forte 5% testosterone creams for men



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



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, 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

1. The effectiveness of transdermal progesterone cream on menopausal symptoms, lipids and bone markers
2. The effects of sequential transdermal progesterone cream on endometrium bleeding pattern and salivary levels in post-menopausal women
3. Evaluation of serum testosterone levels after topical applications of Andro-Feme® cream in post menopausal women with symptoms of testosterone deficiency
4. Systemic absorption after transdermal application of labeled progesterone in rats
5. Plasma and saliva concentrations of progesterone in pre-and postmenopausal women after topical application of progesterone cream
6. The effect of testosterone replacement therapy on sexuality, mood and cognition of post menopausal women
7. Long-Term pharmacokinetics and clinical efficacy of Andromen® Forte 5% cream for androgen replacement in hypogonadal men.
8. Transdermal testosterone therapy improves well-being, mood, and sexual function in premenopausal women.
9. The pharmacokinetics of Andro-Feme® 1% testosterone cream following two week, once daily application in testosterone deficient women.

Recommended Reading for Patients

1. <http://www.manboobs.name>
2. Lawley Pharmaceuticals – <http://www.hormonesolutions.com.au/>
3. Andrology Australia – <http://www.andrologyaustralia.org>
4. Lab Tests Online – <http://www.labtestsonline.org/>
5. National Cancer Institute – <http://www.cancer.gov/>
6. Hormone Foundation – <http://www.medem.com>
7. Gynecomastia.org <http://www.gynecomastia.org>

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7. Clinical Trials for Gynecomastia <http://clinicaltrials.gov/ct2/results?term=gynecomastia>
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9. Testosterone supplementation therapy for older men: Potential benefits and risks – D.A. Gruenewalk and A.M. Matsumoto. *Journal of the American Geriatric Society* 2003; 51(1):101-115
10. Arguments against the Long-Term Use of Combined Androgen Blockade – U.E. Studer, R.D. Mills. *Eur Urol* 1998;34:29-32 (DOI: 10.1159/000052295)

Glossary

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

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.

Anosmia: Lacking all sense of smell, common in children with genetic disorders affecting the sex glands.

Azoospermia: The ejaculate contains no sperm at all.

βhCG: Pregnant women excrete this pregnancy hormone 10 days after conception. Males with carcinoma of the testicles excrete this hormone. Normal males never excrete Beta HCG. If you had an orchiectomy (removal of the testicles) but are still excreting Beta HCG, then there is residual cancer that must be removed.

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

Eunuchoid: A male born infertile who is extremely tall because his bone ends do not fuse due to delayed puberty and continue growing, with long, slender limbs, little or no beard growth, and high-pitched voice.

Fibrosis: Scar tissue replaces healthy tissue as a result of degeneration, injury, or infection.

Genotype: Genetic makeup, as opposed to appearance.

Gonadotropin levels: The pituitary gland secretes a group of hormones called gonadotropins, which stimulate the testicles and ovaries. Boys with Klinefelter syndrome possess at least one extra X chromosome(s), which usually causes their pituitary glands to produce too much of the gonadotropins FSH (follicular stimulating hormone) and LH (luteinizing hormone). FSH and LH suppress the testicles' normal function. Drs. S.K. Advani, M.D. Chadh, and N.M. Khan, endocrinologists in Bombay, reported examining two men in their twenties with 47XXY Klinefelter syndrome who did not have elevated FSH and LH. These doctors suggest all males with suspected Klinefelter syndrome should have a karyotype performed before starting therapy with hCG. If the karyotype test result shows 47 XXY and the serum gonadotropin levels are not elevated, then the males should undergo detailed imaging studies of their pituitary-hypothalamic complexes.

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.

Mastectomy: Surgical removal of the breast.

Oligospermia: The ejaculate contains fewer sperm than normal.

Osteoporosis: Bones that are brittle and break easily due to lack of calcium and sex hormones.

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 testes. The pituitary stimulates the adrenal glands and the thyroid.

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

Virilize: Encourage formation of male secondary sexual characteristics, such as beard growth, voice deepening, and strong muscle growth.

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