

Testosterone for Men

Information on the use of Testosterone in males



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Testosterone Introduction

Testosterone is an essential hormone produced by both men and women that plays a crucial role in the health and well being of our bodies.

Many myths and misunderstandings exist as to the activity and effects that hormones, including testosterone, exert on humans.

Testosterone supplementation was for many years considered a taboo area of medicine especially in women, but focus has shifted in recent years and the benefits to patients have become apparent with controlled scientific research.

Today the variety of treatment options are greater, how testosterone works is better understood and supplemented testosterone treatments are closely monitored and tailored to meet individual requirements.

Not all aspects of testosterone are covered within this website and further advice and information should be sought from your medical practitioner if areas of clarification are required. Health professionals and users requiring more technical information on testosterone use please visit

www.doctordirect.com.au

If you feel you have some of the symptoms mentioned please visit your doctor so he or she can investigate the cause and outline an appropriate course of treatment.



What is Testosterone?

Natural testosterone is a term used to describe the hormone testosterone that is naturally produced by the testes, ovaries and adrenal glands of humans and animals.

This hormone in its pure form is not produced anywhere in the plant kingdom.

Testosterone, or rather the effects of testosterone, have long been recognized as exerting a significant effect on the human body.

For centuries the testes have been identified as the primary source of testosterone production in men. With the advent of pharmaceutical chemistry pure testosterone was first manufactured synthetically in the late 1930's.

Today natural testosterone and synthetic analogues with testosterone-like actions are manufactured for pharmaceutical purposes from soya and wild yam substrates.

Testosterone is classified as an androgen. Androgens are a group of hormones that control masculine sex characteristics. They play a role in maintenance of systemic anabolic effects, particularly metabolism of salts, fluid balance and bone growth.

Testosterone has significant effects on libido, body mass, mood and depression.

Both sexes produce testosterone. Men produce far greater quantities of testosterone than women. The amount secreted by women is small and it does not have a strong masculinising effect.

Testosterone is crucial for the development and maintenance of the male sex organs and the male secondary sex characteristics. These include muscle bulk, facial and axillary hair, changes in fat distribution and deepened voice.

It also produces systemic anabolic effects which include retention of nitrogen, calcium, sodium, potassium, chloride and phosphate. This leads to an increase in water retention and bone growth.

Testosterone makes the skin more vascular and less fatty.



Causes of Testosterone Deficiency

Male hypogonadism is the medical phrase used to describe men with severe testosterone deficiency. The degree of severity of the condition can vary from individual to individual, but there is universal similarity of symptoms in testosterone deficient males - these include fatigue, lethargy, mood changes, ill temper, sexual dysfunction, poor erectile function, loss of sexual interest, diminished muscle strength, osteoporosis and anaemia.

Classical male hypogonadism is most frequently due to primary testicular disease e.g. Klinefelter's syndrome, but may result from malfunctioning of the pituitary gland or hypothalamus in the brain.

Male hypogonadism is estimated to have a prevalence of 5 per 1000 men making it one of the commonest forms of hormonal deficiencies in men.

Physiological androgen replacement aims to restore circulating testosterone concentration to normal in men with hypogonadism.

Common causes for reduced testosterone production that results in a deficiency state include :

Testicular Disorders

- Klinefelter's syndrome
- Cryptorchidism and defects of testis development (Twisted or strangulated testes)
- Orchitis (Inflammation of the testes resulting in permanent damage)
- Orchiectomy (surgical removal of the testes)
- Toxin exposure (radiation, chemotherapy or radiotherapy, domestic, industrial or environmental poisons)

Brain Disorders (Hypothalamic-Pituitary Dysregulation)

- Kallmann's syndrome (a genetic disorder)
- Other genetic causes
- Pituitary gland tumour and treatment (surgery and/or irradiation)
- Haemochromatosis (Blood iron disorder)
- Craniopharyngioma (benign tumour of the brain)



External Factors

- Acute critical illness, burns, major trauma or surgery
- Drug use (eg, opiates, glucocorticoids, anabolic steroids)
- Chronic disease and its treatment
- Alcohol abuse
- Smoking
- Ageing

Regardless of the underlying cause of the testosterone deficiency the treatment is universally testosterone supplementation.

Testosterone replacement therapy (TRT) aims to restore circulating testosterone concentration to normal in men with all degrees of hypogonadism.

TRT is highly effective in restoration of blood testosterone levels to the normal ranges and safely and effectively resolves all symptoms associated with testosterone deficiency.

The use of testosterone in the management in middle aged and older men who exhibit symptoms associated with lowered testosterone levels, but do not have testicular or brain disorders which contribute to their testosterone deficiency is one of the most rapidly expanding areas of medical practice.

It is the Androgen Deficient Ageing Male (ADAM) or late-onset hypogonadal male that is the largest underdiagnosed group of all testosterone deficient individuals. Symptoms are often non-specific, can be confounded by pre-existing medical conditions (obesity, chronic illness) and include lethargy, sleep disturbances, loss of libido, irritability, anxiety, reduced concentration and depressed mood. This individual will usually have a testosterone blood test that is at the bottom end of the "normal" range.



Testosterone Replacement Therapy (TRT)

Testosterone replacement therapy is initiated by a medical practitioner when clinical complaints are accompanied by decreased testosterone levels and confounding factors have been excluded. The aim of therapy is to re-establish normal sexual functioning, and general mental (eg mood, mental acuity) and physical status (eg muscle mass, muscle strength, virilisation) appropriate to age by the most physiological and risk-free means available.

Testosterone replacement restores serum testosterone to physiological circulating concentrations in men with hypogonadism and reverses the symptoms of androgen deficiency. Thus it is able to produce improvement in libido, increase in bone mineral density and in muscle mass, and produces favourable changes in body composition with reduction in fat mass and increase in lean body mass, improvement in mood, correction of anaemia and improvement in memory performance and cognitive status. It is thought that testosterone therapy lessens the risk of cardiovascular disease, but this has not been fully established.

Testosterone Treatment Options

Testosterone has been used for many decades for the treatment of testosterone deficient males.

Today options for treatment include topical testosterone gels and creams, short and long acting injections of testosterone esters, application of testosterone via transdermal skin patches, subcutaneous testosterone implants and oral testosterone capsules.

Injections: Testosterone esters (Sustanon®) must be injected every 2 - 4 weeks, customarily in doses of 250mg. The injection must be deep intramuscular and is quite often painful. The injection results in very high circulating concentrations of testosterone for several days after administration, with a progressive fall to normal or sub-normal concentrations over the succeeding 2 - 3 weeks.

The rise and fall in concentration may be accompanied by fluctuations in the symptoms of androgen excess and deficiency.



Recently longer acting injections (Nebido®/Reandron®) have become available and last for up to three months. They, like the shorter acting injections, are often associated with pain and their effects are irreversible if unwanted side effects occur.

Testosterone skin patches (Androderm®) provide physiological testosterone replacement, with night-time applications leading to a pattern of circulating concentrations similar to that normally seen in healthy males. Patches must be applied daily, and there is a relatively high incidence of adverse skin reactions, which may be sufficiently severe to lead to discontinuation of use. The patches are readily visible and may discourage users from participation in sporting activities, including swimming and other sports requiring the use of change rooms.

Testosterone pellets (implants) in doses of 600 - 1200 mg, are inserted subcutaneously under local anaesthetic. They produce physiological testosterone concentrations which may be sustained for 4 - 6 months. Problems include the need for repeated local surgical procedures, and expulsion of the implants which may occur in 5 - 10% of procedures, often several weeks later. The site of implantation may occasionally become infected which may require antibiotic treatment.

Oral testosterone capsules (Andriol®) provide only moderately effective testosterone replacement, with wide fluctuations in circulating concentrations, due to highly erratic absorption and sometimes gastro-intestinal intolerance. Up to eight 40mg oily capsules daily are required and the use of oral testosterone is generally confined to patients who are intolerant of other preparations.

Topical testosterone gels (AndroGel®/Testogel®, Testim® 1% testosterone gels) and testosterone creams (Andromen®/Andromen® Forte 2% & 5% testosterone cream) require daily application, and provide physiological replacement with few problems and satisfactory efficacy. Well designed studies show the efficacy and safety of this mode of administration to be high when given for an average of 36 months follow-up. Gels and creams have to a large extent replaced the previously mentioned forms of testosterone due to their patient friendly mode of application and flexibility with regards to dose.



In practical terms the gels need to be applied over a very large skin surface area (back, chest, shoulders and arms) compared to the higher concentration creams which require smaller surface areas for application (fore and upper arms, torso and thigh).

Scrotal application of the testosterone cream does not meet with discomfort in patients, whereas the alcohol-based gel creates a burning sensation when applied to the genitalia.

Potential Risks of Testosterone Treatment (Short and Long Term)

Testosterone should not be used in men with breast cancer or known or suspected prostate cancer.

Patients with heart disease, liver disease or kidney disease are not recommended to use testosterone supplements.

Before initiating TRT your doctor should check for prostate abnormalities by means of a digital rectal examination (insertion of the finger through the anus and feeling the hardness of the prostate gland) and a blood test for Prostate Specific Antigen (PSA).

These tests will ensure complications of the prostate should not arise due to testosterone usage.

Side effects can occur if testosterone is used in excess quantities.

These may include:

- Too frequent or persistent erections of the penis (priapism)
- Nausea and vomiting
- Swelling of the ankles
- Acne
- Headache
- Gynecomastia (breast development)
- 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.

Prostate Disease

A. Benign prostatic hyperplasia (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.

B. 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. 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 medications.

Coronary Heart Disease

A major theoretical concern regarding testosterone administration is the possibility that it could increase the risk of cardiovascular disease. Such a concept is based on the higher incidence of cardio vascular events in men than in women. However, this may be much more readily explicable by protective effects of estrogen in women. There is little data to support a causal relationship between high testosterone levels and heart disease and 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 vasodilation following intra-coronary injections of testosterone. There are no reports of increasing incidence of cardio vascular disease including myocardial infarction, stroke 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 intra muscular route (injections), where high serum testosterone levels are present for some days following each injection, is the occurrence of polycythemia, with a rise in haematocrit (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 normalisation.



There is a direct dose relationship between 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.

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.

Testosterone Check List


- Identify symptoms
- Consult your local medical professional
- Exclude other factors that may cause symptoms
- Have serum testosterone parameters checked
- Have prostate gland checked.
- If required commence three month trial of testosterone
- Have regular monitoring of treatment by a medical professional

To learn more about the use of testosterone please visit

www.lawleypharm.com.au



Testosterone for Men - Quick Q & A

- Q.** How do I know if I need testosterone?
- A.** You may have noticed changes in your mood, your thoughts, your muscle strength, your body shape, your sexual arousal and/or sexual function and your energy levels. Changes in these areas provide the clues to a low testosterone. Your doctor can do a blood test to confirm levels are in the lower range. Taking the self assessment questionnaire will also establish the need for testosterone supplementation.
- Q.** How long after starting Andromen® Forte or Andromen® testosterone cream will I notice an improvement?
- A.** Once commencing Andromen® Forte or Andromen® testosterone levels rise within an hour. It usually takes 1 - 2 weeks for the full benefits of treatment to become apparent.
- Q.** How often do I use Andromen® Forte or Andromen® testosterone cream?
- A.** Andromen® Forte and Andromen® testosterone cream for men is used once daily, usually applied in the morning.
- Q.** Where do I apply Andromen® Forte and Andromen® testosterone cream for men?
- A.** Andromen® Forte and Andromen® testosterone cream for men is applied to the scrotum. The cream is massaged into to scrotal skin and usually is fully absorbed within 30 seconds of application. There are no benefits of applying Andromen® Forte or Andromen® to the penis. Often there is a 'warm' feeling of the scrotum after applying Andromen® Forte or Andromen® – this is due to a dilation of the blood vessels in the scrotal skin. This effect is not unpleasant and usually lasts for only a few minutes.
- Q.** What safety checks do I need before starting Andromen® Forte or Andromen® testosterone cream?
- A.** Your doctor needs to undertake a physical examination of your prostate gland and conduct a blood test to measure the PSA (prostate specific antigen). This is to ensure that you do not have prostate cancer. Testosterone should not be used if there is prostate cancer or irregularities. If you have chronic liver or kidney disease testosterone should only be used with strict medical supervision.
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- Q.** For how long do I use Andromen® Forte or Andromen® testosterone cream?
- A.** There is no time limitation to using Andromen® Forte or Andromen® testosterone cream. However your doctor should conduct regular six-monthly medical checks, including PSA and prostate gland examination.
- Q.** If I stop using Andromen® Forte or Andromen® how quickly will the testosterone be out of my system?
- A.** Once supplementation with Andromen® Forte or Andromen® testosterone cream is stopped blood testosterone levels will fall to baseline levels within 72 hours. Pre-treatment symptoms will usually return with this decline of the blood testosterone levels.
- Q.** Why is Andromen® Forte and Andromen® less expensive than other forms of testosterone treatment?
- A.** Scrotal skin is up to 40 times more receptive to the absorption of testosterone than when applied to skin areas such as the back, body and arms. Andromen® Forte testosterone cream for men is unique because it is easily be applied to the scrotum without complications whereas other transdermal testosterone preparations on the market cannot be applied to the genitals. Andromen® Forte is a 5% testosterone cream compared to the 1% testosterone gels commercially available and therefore being more concentrated Andromen® Forte allows for a smaller unit dose. On a \$ cost per daily dose Andromen® Forte treatment costs between US\$1 - 2 per day whereas other competitor products approximate to US\$7 - 8/day.
Ref: www.drugstore.com
- Q.** How long will a tube of Andromen® Forte testosterone cream last?
- A.** A single 50 gram (approx 2 oz) tube of Andromen® Forte testosterone cream for men will provide between 50 - 100 days treatment depending upon the dose used.



- Q.** Do I use Andromen® Forte 5% testosterone or Andromen® 2% testosterone cream?
- A.** Both Andromen® Forte and Andromen® testosterone creams have the same base cream. The only variable is the concentration of the testosterone – 5% and 2% respectively. Both products will achieve significant rises in blood testosterone levels and the main consideration in choosing is the cost of the product. For men the more cost effective purchase is Andromen® Forte 5% testosterone cream.
- Q.** Do I need a doctor's prescription for Andromen® Forte or Andromen®?
- A.** Yes, in Australia a doctor's prescription is required to obtain Andromen® Forte and Andromen testosterone cream. It is imperative that your doctor checks the prostate gland prior to starting Andromen® Forte 5% or Andromen® 2% testosterone cream.

To learn more about testosterone for men, testosterone for women or progesterone for women log onto www.lawleypharm.com.au

Or call **Lawley Pharmaceuticals** on **+61 (08) 9228 9033** or **1800 627 506**.



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