Testosterone For Men

Information on the use of testosterone in males

LAWLEY Hormone Solutions

Contents

Testosterone Introduction

Testosterone is an essential hormone produced by both men and women. It 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 for many years was considered a taboo area of medicine, due primarily to side effects following abuse by athletes and body-builders using super potent anabolic steroids. However, focus has shifted in recent years and the benefits of pure testosterone (not synthetic anabolics) for patients has become apparent with controlled scientific research.

Today, the variety of treatment options is greater, how testosterone works is extremely well understood and the newer testosterone treatments are more refined and tailored to meet individual requirements.

Not all aspects of testosterone are covered within this booklet. Further advice and information should be sought from your medical practitioner if areas of clarification are required. For health professionals and users requiring more technical information on testosterone use in men, please visit www.hormonesolutions.com.

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

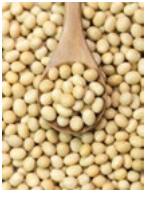
What is Testosterone?

Natural testosterone is a term used to describe the hormone testosterone that is naturally produced by the testes in men.

Testosterone has long been recognized as exerting a significant effect on the human body.

For centuries, the testes have been identified as the primary source of sexual potency and virility in men. In the early 1900s the hormone testosterone was identified. With the advent of pharmaceutical chemistry, pure testosterone was first manufactured synthetically in the late 1930s.

Today, natural testosterone and synthetic analogues with testosterone-like actions are manufactured for pharmaceutical purposes from soya substrates in laboratories. Pure testosterone is not found in plants.



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

In men, testosterone exerts a positive effect on libido, sexual function, body shape and muscle mass, mood, energy levels and depression.

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 deepening of the 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 (better blood flow) and less fatty.

Causes of Testosterone Deficiency

Male hypogonadism is the medical phrase used to describe men with a testosterone deficiency. The severity of the condition can vary from individual to individual. However, there is universal similarity of symptoms in testosterone deficient males. These include:

- fatigue
- lethargy
- lack of motivation
- poor memory
- mood changes
- ill temper
- depression
- sexual dysfunction
- poor erectile function
- loss of sexual interest
- diminished muscle strength
- osteoporosis
- anemia

Male hypogonadism is most frequently due to testicular damage, disease or genetic disorder (primary hypogonadism) e.g. Klinefelter syndrome. It may also result from malfunctioning of the pituitary gland or hypothalamus in the brain (secondary hypogonadism).

Primary and secondary hypogonadism has a prevalence of 5 cases per 1000 men. This makes it one of the most common forms of hormonal deficiencies in men, yet only one in five men are diagnosed early in life.

Testosterone replacement therapy (TRT) effectively restores blood testosterone concentrations in men with hypogonadism to the normal levels of healthy young males.

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

Testicular Disorders

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

Brain Disorders (Hypothalamic-Pituitary Dysregulation)

- Kallman syndrome (a genetic disorder)
- Other genetic causes
- Pituitary gland tumor and treatment (surgery and/or irradiation)
- Hemochromatosis (blood iron disorder)
- Craniopharyngioma (benign tumor of the brain)

External Factors

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

More recently, a third class of hypogonadal men have been identified and defined. The late-onset hypogonadal male is the largest under-diagnosed group of all testosterone - deficient individuals. This group consists of middle-aged and older men who exhibit symptoms associated with lowered testosterone levels, but do not have primary or secondary hypogonadism. This is one of the most rapidly expanding areas of medical practice. Recent medical studies show as many as 37% of all men over the age of forty have symptoms of testosterone deficiency.

The late-onset hypogonadal male's symptoms are often non-specific. They include lethargy, sleep disturbances, loss of libido, irritability, anxiety, reduced concentration and depressed mood. This individual will usually have a testosterone blood test result at the bottom end of the "normal" range. This may often result in a medical practitioner prescribing antidepressants to treat symptoms rather than the underlying cause. Diagnosing the symptoms which many men experience due to late-onset hypogonadism can be further complicated by pre-existing medical conditions such as obesity, diabetes and chronic illness.

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 within the normal healthy male range with the absence of symptoms. TRT safely and effectively resolves most, if not all, symptoms associated with testosterone deficiency.

Symptoms	None	Mild	Moderate	Severe	Extremely Severe
Decline in your feeling of general well-being (general state of health, subjective feeling)	○	○	○	○	○
Joint pain and muscular ache (lower back pain, joint pain, pain in a limb, general back ache)	○	○	○	○	○

Complete the Aging Male Symptoms (AMS) questionnaire online at www.hormonesolutions.com/quizzes/male.

How is Testosterone Deficiency in Men Diagnosed?

There are two key parameters which determine if a man requires testosterone replacement – his testosterone blood level and the range and severity of his symptoms.

Symptoms

There are a host of symptoms commonly associated with testosterone deficiency in men, which may appear unrelated to each other. Consequently, many doctors fail to "join the dots" in identifying testosterone deficiency. Most doctors experienced in treating late-onset hypogonadism will use an assessment questionnaire such as the Aging Male Symptoms (AMS) Questionnaire www.hormonesolutions.com/quizzes/male.

The AMS questionnaire is a 17 question self-rating symptom-based questionnaire with three key domains of assessment - mind (5 questions), body (7 questions) and sexual (5 questions). Responses to each question are assigned a rating between one (none) to five (extremely severe). The total sum of all subscales provides a total score. Scores can range from a total low of 17 to a maximum of 85, with a complaint score measuring greater than 50 considered severe.

The AMS questionnaire is well suited to assist in both the diagnosis of testosterone deficiency and for the

monitoring of treatment in patients using testosterone replacement therapy.

Whether due to testicular failure, brain disorder or aging, the signs and symptoms as a result of testosterone deficiency are consistent.

Testosterone deficient men may exhibit some or all of the following:

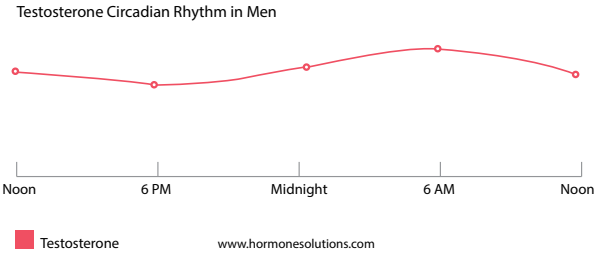
- Changes in mood (fatigue, depression, anger)
- Decreased body hair (feminization)
- Decreased bone mineral density and possible resulting osteoporosis
- Decreased lean body mass and muscle strength
- Decreased libido and erectile quality
- Increased abdominal fat
- Rudimentary breast development (man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

Gauging the severity of symptoms via the use of the AMS rating scale provides a yardstick for both patients and doctors to measure the success of testosterone treatment.

Blood Testing

The measurement of testosterone levels in the blood provides a snapshot of what the testosterone status of the person is at the time of taking blood.

Testosterone secretion follows a diurnal rhythm in men. That is, it rises and falls over a 24 hour period. Testosterone production occurs during the night and early morning with levels highest on waking. This higher level of testosterone in the morning explains why healthy men generally experience an early morning erection. Serum testosterone levels slowly decrease during the day and are lowest in the late afternoon and early evening.



Therefore, blood samples should preferably be taken in the morning when testosterone levels are at their highest. Individual variations in serum testosterone levels can occur due to time of day, medication usage, stress, illness or recent surgery.

The testes do not store testosterone. Once produced, testosterone is secreted into the blood stream where it is rapidly adhered to by the protein 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 and inactive. Testosterone to which SHBG does not attach is the biologically available testosterone that is free to act on and enter into cells throughout the body. This "free testosterone" is crucial in determining how efficiently testosterone can have an impact upon the cells and tissue of the body.

Some doctors will measure only total testosterone levels (i.e. both free and SHBG bound testosterone). Measuring total testosterone does not take into account the SHBG levels. While not technically wrong, total testosterone measurement alone is not the most accurate representation of how much testosterone is free to act in the body. As a consequence, the total testosterone reference ranges commonly adopted by pathology laboratories for determination of "normal" and "low" testosterone are potentially misleading. This is because the results do not take into account the effects of SHBG. SHBG is elevated with age, smoking, high alcohol intake, insulin and some medications.

It is always best to measure both the "total" and the "free" or "calculated free" testosterone in the blood if the lab has the technical capacity to do so. An alternative option which takes into account SHBG levels is the "free androgen index" or FAI. This is calculated by the total testosterone level in the blood divided by the SHBG level multiplied by 100. Pathology labs will automatically do this calculation and the result will be the FAI reading. Generally, in men a FAI reading of 75 or less is a strong indication testosterone supplementation is warranted, if the AMS score is also high.

The table below provides a guide to the "normal" ranges in men for the most common components measured in blood.

		UNIT OF MEASURE	NORMAL ADULT MALE
Complete Blood Count (CBC)	Red Cells	million/mm^3	4.7 to 6.1
	White Cells	million/mm^3	5,000 to 10,000
	Hemoglobin	g/dl	14 to 18
	Hematocrit	%	42 to 52
	Platelets	mm^3	150,000 to 400,000
	MCV	μm^3	80 to 95
	MCH	pg	27 to 31
	MCHC	%	32 to 36
	Retics	% of total RBC	0.5 to 2
Iron Studies	Serum Iron	µg/dl	60 to 190
	Ferritin	ng/mL	123
	TIBC	µg/dl	250 to 420
Thyroid Profile	T3	ng/dL	110 to 230
	T4	µg/dL	5 to 10
	TSH	µU/mL	1 to 4
Liver Profile	AST	IU/L	5 to 40
	ALT	IU/L	5 to 35
	ALP	ImU/mL	30 to 85
	Bilirubin	mg/dL	0.1 to 1.0 150
	Cholesterol	mg/dL	to 250
Kidney Profile	Creatinine	mg/dL	0.57 to 1.00 7
	BUN	mg/dL	to 20
Adrenal Profile	Cortisol	µg/dL	4.3 to 22.4
	ACTH	pg/mL	6 to 48

		UNIT OF MEASURE	NORMAL ADULT MALE
Sex Hormones	GH	ng/mL	0 to 8
	FSH	mIU/mL	1.4 to 18.1
	LH	mIU/mL	1.5 to 9.3
	HCG	mIU/mL	0
	Progesterone	ng/mL	<1
	Oestradiol	pg/mL	<54
	Prolactin	ng/mL	< 20
	Testosterone	ng/dL	375 to 1,200 USA
	Free testosterone	pg/mL	50-175 USA
	SHBG	nmol/L	6 to 50
	Free Androgen Index (FAI)		> 75

These are guidelines only. Your laboratory adjusts its normal values for the local population it serves. It may use different units of measure.

It is essential the diagnosis and a decision of whether to use testosterone is NOT made on the result of a blood test alone. Nearly all men with a total or free testosterone result at the low end of the normal range and experiencing symptoms will positively respond to testosterone replacement. They will also achieve a significantly improved quality of life. Unfortunately, too many doctors see a reading in the "normal" range and dismiss testosterone as a treatment option. All too often antidepressants are prescribed. This achieves little by way of elevating mood and usually results in a more rapid decline of sexual function.

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, general mental health (e.g. mood, mental acuity, clear thinking) and physical status (e.g. muscle mass, muscle strength, virilization) 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 an improvement in libido, an increase in bone mineral density and an increase in muscle mass. Testosterone produces favorable changes in body composition, with a reduction in fat mass and an increase in lean body mass; improvement in mood; correction of anemia; and improvement in memory performance and cognitive status. It is widely accepted testosterone therapy lessens the risk of cardiovascular disease. Some cardiologists routinely prescribe testosterone to their patients when testosterone levels are low or following heart attacks.

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 must be injected every two to four weeks, customarily in doses of 250mg. The injection must be deep intramuscular and is quite often painful. It results in very high circulating concentrations of testosterone for several days after administration,

with a progressive fall to normal or sub-normal concentration over the following two to three weeks.

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

More recently, longer acting injections (Reandron®) have become available and last for up to three months. They are not available in the USA. These longer acting injections, 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. Night-time applications lead to a pattern of circulating concentrations similar to what is 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 visible and may discourage users from participation in sporting activities which require 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 four to six months. Problems include the need for repeated local surgical procedures, and expulsion of the implants. Expulsion may

occur in 5 to 10% of procedures, often several weeks later. The site of implantation may occasionally become infected and require antibiotic treatment.

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

Topical testosterone: (Testogel® 1%) testosterone gels and testosterone creams (AndroForte® 2 & 5% testosterone creams) 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 require application over a very large skin surface area (back, chest, shoulders and arms). Patients need to wear covering clothing on the site of application when in contact with partners or children to avoid transfer of residual testosterone from the skin.

Testosterone creams (Lawley Pharmaceuticals, Australia) are unique topical preparations because they can be applied directly to the scrotum. Scrotal skin is up to five times more receptive to the absorption of testosterone than upper body skin. Therefore, a lower testosterone dose can be used to achieve a higher blood testosterone level.

Scrotal application of the testosterone cream does not cause discomfort in patients, whereas the alcohol-based gels create a burning sensation and skin irritation. The risk of cream transfer to others is minimal.

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 severe unstable heart disease, severe liver disease or severe kidney disease are not recommended to use testosterone supplements unless under close medical supervision.

Before initiating TRT, your doctor should check for prostate abnormalities by means of a digital rectal examination and a blood test for Prostate Specific Antigen (PSA).

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

Side effects can occur if testosterone is used in excessive 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 from an 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.

Many medical studies have failed to show any deterioration in obstructive symptoms attributable to benign prostatic hyperplasia during treatment with testosterone. Urinary retention has not been reported at rates higher than in control subjects.

B. Prostate cancer: One of the biggest myths in men's health today is testosterone treatment increases the risk of developing prostate cancer. Whilst lowering of testosterone levels is a standard treatment for metastatic prostate cancer, there is no evidence to suggest replacement of low testosterone levels into the normal range leads to any increase in the occurrence of the disease. Numerous medical studies unequivocally show there is no significant increase in the occurrence of prostate cancer and a variable increase in the levels of prostate specific antigen (PSA). The authors of one paper concluded, "there is no compelling evidence that testosterone has a causative role in prostate cancer... (nor) increases the risk". As part of the routine monitoring of testosterone replacement therapy, regular digital rectal examination and measurement of PSA are recommended.

Moreover, the evidence is becoming clear that men with low testosterone are more likely to develop prostate cancer; and testosterone plays a protective role on the prostate.

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 it could increase the risk of cardiovascular disease.

Such a concept is based on the higher incidence of cardiovascular events in men than in women. However, this may be much more readily explicable by the protective effects of estrogen, a hormone found in much higher quantities 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 the opposite may be true - men with low testosterone levels may be at higher cardiovascular risk. There are reports testosterone replacement can improve symptoms of chronic stable angina. There are direct observations showing vasodilation following intra-coronary injections of testosterone. There are no reports of increasing incidence of cardiovascular disease including myocardial infarction, stroke or angina in reports of testosterone replacement therapy.

Polycythemia (an abnormal increase in red blood cells)

A well known side effect of chronic testosterone administration is the occurrence of polycythemia, with a rise in hematocrit (the percentage of whole blood composed of red blood cells). This is particularly common when the intra-muscular route (injections) is used and high serum testosterone levels are present for some weeks following each injection. Men with hypogonadism tend to have anemia and reduced hematocrit concentrations. In these men, testosterone replacement leads to normalization.

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. If polycythemia occurs, a reduction of the dose of testosterone is required and/or phlebotomy (drawing of blood) to reduce the red blood cell count and resolve the situation.

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 (AMS questionnaire)
- Consult your local medical professional
- Exclude other factors that may cause symptoms
- Have free and total testosterone levels checked
- Have prostate gland checked (PSA and physical exam)
- If required, commence a three month trial of testosterone then review
- Have regular monitoring of on-going treatment by a medical professional

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 low testosterone. Your doctor can do a blood test to confirm levels are in the lower range. Taking the self assessment Aging Male Symptoms (AMS) questionnaire will also help establish the possible need for testosterone supplementation.

Q. How long after starting AndroForte® 2 or AndroForte® 5 testosterone cream will I notice an improvement?

A. Once commencing testosterone cream, testosterone levels rise within an hour. It usually takes two to four weeks for the full benefits of treatment to become apparent.

Q. How often do I use AndroForte® 2 or AndroForte® 5 testosterone cream?

A. AndroForte® 2 or AndroForte® 5 are applied once daily (usually in the morning) directly to the scrotum.

Q. Where do I apply AndroForte® 2 or AndroForte® 5?

A. AndroForte® 2 and AndroForte® 5 testosterone cream are applied to the scrotum. The cream is massaged into the scrotal skin and usually is fully absorbed within 30 seconds of application. There are no benefits of applying the cream to the penis. Often there is a 'warm' feeling after applying the cream – this is due to 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 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 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 under strict medical supervision.

Q. For how long do I use AndroForte® 2 or AndroForte® 5 testosterone cream?

A. There is no time limitation to using testosterone cream. However, your doctor should conduct regular six-monthly medical checks, including PSA and prostate gland examination. A full health check including hematocrit (percentage of red blood cells) and liver function tests should be completed every 12 months.

Q. If I stop using AndroForte® 2 or AndroForte® 5 testosterone cream, how quickly will the testosterone be out of my system?

A. Once supplementation with 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. Does scrotal application of testosterone result in conversion of the testosterone to dihydrotestosterone (DHT) and/or estradiol (E2)?

A. Testosterone conversion to estrogen and dihydrotestosterone (DHT) is, in clinical terms, not a major problem provided no more than the recommended dose of testosterone cream is used. In scrotal skin there is an enzyme called 5-alpha-reductase which may convert testosterone into the more potent androgen DHT. However, this conversion is generally very

small. Men with low testosterone levels also have low DHT levels. When they use scrotal testosterone cream their DHT blood level usually increases by a small amount to the mid-range of normal. Similarly, the enzyme aromatase can convert testosterone into estradiol (E2). Again, if the recommended dose of testosterone cream is used, conversion to E2 is usually not a problem. There is no evidence of gynecomastia (male breast growth) due to E2 conversion in men using testosterone cream. There is a large amount of misinformation on the Internet about testosterone conversion and most is unfounded - the science does not support the theory. The science does show there is a small, but insignificant rise in both estrogen and DHT levels with initial use of scrotal testosterone. In the vast majority of patients this rise is within the normal range for men. A simple dose reduction is required if levels do rise beyond the normal range. There is no need to take aromatase inhibitors or 5-alpha-reductase inhibitors when commencing treatment. However, feel free to consult with your doctor. If concerned, it is advised to have E2 and DHT levels checked together with hematocrit, PSA and a prostate gland examination by your doctor, every six to 12 months when regular testosterone blood levels are being monitored.

Q. Does using testosterone result in shrinkage of testes?

A. The short answer is 'no'. Testosterone cream will not cause testicular atrophy (shrinkage) if used in the correct doses. Part of the "historical myth" of testosterone being dangerous is due to it being lumped in with the 'anabolic steroids story'. Testosterone has anabolic actions, but nothing relative to many of the synthetic anabolic steroids used and abused by athletes and bodybuilders. Unfortunately, testosterone is mistakenly thought to possibly cause atrophy (shrinkage) of the testes when used in therapeutic doses - this is not the case. Potentially, if massive doses were used for weeks continuously, there may be some adverse effect.

Q. If I stop using testosterone, what will happen to my testosterone blood levels?

A. When using testosterone cream, your testosterone levels will rise above your low baseline level to a new higher level. Provided you continue to use the testosterone daily, the new higher level will remain constant. If you stop using the testosterone cream your testosterone blood levels will return to their baseline level within a week. Symptoms will most probably return.

Q. Why are AndroForte® 2 and AndroForte® 5 testosterone creams applied scrotally and the gels applied to the upper body?

A. Scrotal skin is up to five times more receptive to the absorption of testosterone than when applied to skin areas such as the back, body and arms. AndroForte® 2 and AndroForte® 5 for men are unique because they are easily applied to the scrotum without complications. Other transdermal testosterone preparations on the market cannot be applied to the genitals due to skin irritation. AndroForte 5% testosterone cream is five times stronger compared to the 1% testosterone gels commercially available. Therefore, being more concentrated AndroForte 5% testosterone cream allows for a smaller unit dose to be applied over the small surface area of the scrotum.

Q. How long will a tube of the AndroForte® 2 or AndroForte® 5 testosterone cream last?

A. A single 50ml (approx 2oz) tube of the AndroForte® 2 or AndroForte® 5 testosterone cream will provide between 50 to 100 days treatment depending upon the dose used.

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.

AndroFeme® 1% testosterone cream for women

AndroForte® 2% and 5% testosterone creams for men

ProFeme® 3.2% and 10% progesterone creams for women

Our Mission Statement

Lawley Pharmaceuticals (www.hormonesolutions.com) strives to provide the optimal delivery systems for the administration of the naturally occurring human hormones (testosterone, progesterone, estradiol and estriol) to counter endocrine deficiency states. Our philosophy is to use a natural hormone in preference to a synthetic hormone, when it is a viable clinical option. We aim to advance clinical research of natural hormones. Our goal is to establish through evidence-based medical research, naturally occurring hormones as cornerstone treatments for diseases such as breast cancer, infertility, first-term miscarriage, male hypogonadism, post-partum depression and endometriosis. Lawley Pharmaceuticals has established strong links with centers of research excellence around the world and continues to push the boundaries of medical research.

Completed Clinical Studies

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

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

3. Plasma and saliva concentrations of progesterone in pre- and postmenopausal women after topical application of progesterone cream. *O'Leary PJ et al. Presented at the Annual Congress of the Australian Menopause Society held in Perth, Australia in October 1997.*

4. Long-term pharmacokinetics and clinical efficacy of ANDROMEN® FORTE 5% cream for androgen replacement in hypogonadal men *Handelsman DJ et al. ANZAC Research Institute, Department of Andrology, Concord Hospital, Sydney, 2004.*

5. Transdermal testosterone therapy improves well-being, mood, and sexual function in premenopausal women. *Goldstat R et al. Menopause 2003; 10 (5): 390-398.*

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

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

8. Pharmacokinetics of ANDROMEN® FORTE 5% Cream: A Dose Finding Study. *Kelleher S et al. ANZAC Research Institute, Department of Andrology, Concord Hospital, Sydney, 2002.*

9. The Pharmacokinetics of ANDROFORTE® Compared With AndroGel® (Testogel®) in Androgen Deficient Men. *Wittert G et al. Adelaide Awaiting publication.*

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