

# Testosterone For Women

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



**LAWLEY**

Hormone Solutions



## Contents

Testosterone Introduction	4
What is Testosterone?	6
History of Testosterone Use in Females	7
Causes of Testosterone Deficiency	10
Signs and Symptoms of Testosterone Insufficiency	14
Testosterone for Women – Treatment	16
Medical History Including Sexual History	17
Examination	18
Hormone Blood Testing	18
Testosterone Treatment Options	22
Risks of Testosterone Treatment in Women	22
Testosterone for Women – Quick Q & A	25
About Lawley Pharmaceuticals	28
Our Mission Statement	29
Completed Clinical Studies	30
Copyright Information	32

## Testosterone Introduction

“I couldn’t care if I never had sex again”

“I’m too tired”

“Forget the sex, I just wish I had some energy”

“I sleep for eight to nine hours and wake up feeling like I need three hours more”

“I do it for him, not for me”

“I love him, but I just don’t want to have sex with him”

“It’s all just too much, I’d rather get a good night’s sleep”

These comments are repeated by thousands of women every day, sometimes to doctors, sometimes to friends and sometimes to partners.

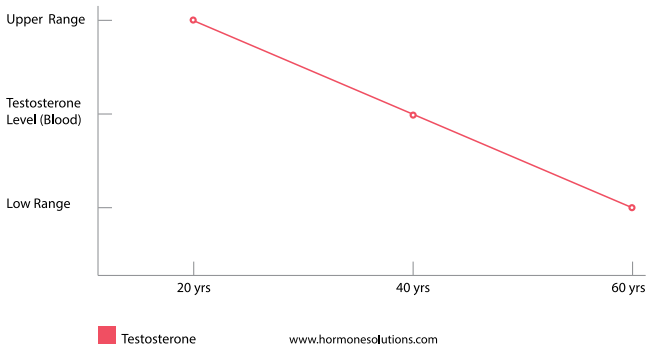
Women provide a far more complex sex-hormone picture than men, with three hormones contributing to the overall makeup of their hormonal balance.

Women produce estrogen, progesterone and testosterone. The ovaries produce the bulk of estrogen during the years leading up to menopause and substantially less post-menopause.

During the menstrual years, progesterone is produced once ovulation has taken place. Progesterone ceases to be produced when ovulation stops at menopause. In some females, progesterone production stops even before menstruation ceases.

Testosterone in women is produced by the ovaries and adrenal glands on a continual basis. Testosterone blood levels are at their highest around age 20 and decline steadily with time. At the age of 40 a woman’s serum testosterone levels are approximately half what they were at age 20. This level continues to fall with age.

### Testosterone Levels in Women



Testosterone is vital in the preservation of bone, for its positive effect on libido and for maintenance of energy levels.

Reduced libido, unexplained fatigue, depression, lack of concentration and emotional mood changes typify the symptoms of testosterone deficiency in women.

Supplementing small amounts of testosterone in women experiencing symptoms of testosterone deficiency usually results in increased energy, libido and sexual response for the patient.

In the last decade there has been an increasing interest in administering low doses of testosterone to pre and post-menopausal women, particularly to help with loss of libido. The use of testosterone to manage low libido in women has extensively been reviewed in medical literature for decades.

## What is Testosterone?

Natural testosterone is a term used to describe the hormone testosterone that is naturally produced by the testes in men and the ovaries and adrenal glands in women.

Testosterone is not produced anywhere in the plant kingdom.

Testosterone has, for over 80 years, been recognized as exerting a significant effect on the human body.



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 and wild yam substrates.

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

Testosterone has significant effects on libido, mood, sexual function 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 masculinizing effect.

Women produce 5–10% of the quantity of testosterone produced by men.

Even though the amount secreted by women is small compared to males, it plays a pivotal role in the sexuality and metabolic functioning of women.

## History of Testosterone Use in Females

There is universal acceptance amongst reproductive endocrinologists, gynecologists and those specializing in the area of women's health that female sexual dysfunction (FSD) affects a substantial proportion of women.

FSD has significant psychological ramifications and can adversely affect social and personal relationships. Various studies indicate 30–43% of women aged between 18 to 59 years experience some degree of sexual dysfunction. Of these women, 18–22% list low libido as their primary symptom.

Classifications and the defining of criteria for sexual dysfunction in women have been established over a decade ago. Validated assessment scales and questionnaires, such as the Female Sexual Function Index (FSFI), have been developed to assist with the diagnosis and monitoring of management regimes for sexual dysfunction.

Female sexual dysfunction is a multifactorial condition requiring careful evaluation. Treatment may involve several management strategies. The hormonal profile of the subject is part of the assessment to determine the origins of sexual dysfunction.

The greatest influence on human sexual function is the hormone testosterone.

Testosterone is a vital component of female sexuality, enhancing desire to initiate sexual activity and intensifying the response to sexual stimulation. It is associated with greater well-being and increased energy and vitality. Testosterone also plays a part in reducing anxiety and depression.

Surgically menopausal women (hysterectomized women with ovaries removed) and women with premature ovarian failure (early menopause) are among the populations most likely to experience a testosterone deficiency. This syndrome is characterized by blunted or diminished motivation, persistent fatigue and lethargy, decreased sense of

personal well-being, low-circulating blood testosterone levels and low libido.

In contrast to estrogen, serum androgen levels do not fall precipitously at the time of menopause, but rather decline with age.

Early scientific evidence from the 1940s and 1950s showed testosterone was the libido-enhancing hormone in the human female.

In the mid-1970s, the vital role of the ovary in testosterone production was established. Subsequent research has recognized sexual function declines following oophorectomy (surgical removal of the ovaries). Additional research has found administration of testosterone reverses the decline in sexuality experienced after an oophorectomy.

Prior to 2000, the majority of medical research conducted regarding testosterone use in women had centered on testosterone implants and injections. While therapeutically effective, these dose forms have significant shortcomings when used in women.

Testosterone implants and injections produce extremely high serum levels in women even when administered in reduced doses. This can often result in levels 10 times higher than normal. At high levels, testosterone has the potential to cause significant side effects including masculinization, hirsutism (body hair growth), acne and voice changes.

Many women who suffer from loss of libido date their problem to removal of their ovaries (oophorectomy) and/or uterus (hysterectomy). Removal of the ovaries in both pre and post-menopausal women results in an immediate 50% reduction in circulating serum testosterone levels.

Standard medical practice over the past 40 years has been to supplement women with estrogen after removal of the ovaries, but ignore the hormones testosterone and progesterone.

Estrogen therapy alone usually does not restore lost libido in oophorectomized women. Medical studies comparing estrogen alone versus estrogen plus testosterone have shown a significant improvement



in energy and libido with the combined treatment. Combination therapy did not show an increase in side effects. Additional medical trials have also shown testosterone has an additive effect on bone density when combined with estrogen –a very important consideration for prevention of osteoporosis.

The problem of reduced libido and unexplained fatigue is not confined to women who have undergone surgical removal of the ovaries.

Pre and post-menopausal women with intact ovaries can also have low testosterone levels and experience the same symptoms of low sexual desire and lethargy as oophorectomized women. Small doses of testosterone can result in significant improvements in quality of life and sexual fulfillment for these women.



In the USA, Europe, Asia, and South America no testosterone product has been government-approved for the treatment of poor libido in women. As a result, testosterone products approved for use in men are often given to women in reduced doses. This is commonplace by doctors around the world—a practice called “off-label” usage.

The most popular options used in women off-label are injectable short acting testosterone depots, testosterone implants or compounded creams or troches from compounding pharmacies.

There are no published trials using injectable testosterone in this way for testosterone therapy in women.

Testosterone implants were discontinued world-wide in 2012.

The situation in Australia is distinctly different with a 1% testosterone cream for women available. (Lawley Pharmaceuticals, Australia [www.lawleypharm.com.au](http://www.lawleypharm.com.au)). It is called AndroFeme®.

AndroFeme® is a popular testosterone option for use in women because it involves no surgery, no pain, has no adhesion or visibility problems and the dose is flexible and accurately controlled.

## Causes of Testosterone Deficiency

- Disruption to Testosterone Production
- High Sex Hormone-Binding Globulin (SHBG) Levels
- Estrogen Tablets and Oral Contraceptives
- Non-Hormonal Drug Therapies

## Disruption to Testosterone Production

When areas in the body responsible for directly or indirectly producing testosterone (the ovaries, the brain and the adrenal glands) are diseased or compromised, the result is a significant reduction in blood testosterone levels.

If both ovaries are removed (bilateral oophorectomy) or premature ovarian failure occurs, there is an immediate 50% reduction in testosterone levels.

If the adrenal glands are removed (adrenalectomy) there is also a 50% reduction in testosterone levels.

If certain areas of the pituitary gland in the brain are affected by disease or damaged (hypopituitarism), the chemical messengers that stimulate the adrenals and ovaries to produce testosterone are affected. This can result in as much as a 100% decrease in testosterone production.

## High Sex Hormone-Binding Globulin Levels

Sex hormone-binding globulin (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 in the body is bound to SHBG. Once testosterone is bound to SHBG (bound testosterone), it is inactive.

Testosterone to which SHBG does not attach is biologically available testosterone. This is free to act on cells throughout the body (free testosterone or free T). Free testosterone is the vital component to measure when having a blood test. Measuring total testosterone alone is not an accurate determination of the amount of “free” testosterone present.

Because SHBG has such a significant effect on testosterone, it is essential SHBG levels be considered when doing blood tests. High SHBG will result in free testosterone being low, hence the underlying cause of lowered energy and libido. For more information on hormone blood testing, turn to page 18.

### **Factors which increase SHBG and lower free testosterone include:**

- Oral estrogen (including oral contraceptives, HRT tablets)
- Thyroxine tablets
- Increasing age
- Alcohol
- Smoking
- Some anticonvulsants e.g. phenytoin
- Pregnancy
- Reduced liver function

## Estrogen Tablets and Oral Contraceptives

There is a very close relationship between the hormones testosterone and estrogen. The standard form of estrogen supplementation used in hormone replacement therapy (HRT) and for oral contraception (the Pill) is the estrogen tablet. Taking oral (by mouth) estrogen increases the effect of sex hormone-binding globulin (SHBG). SHBG binds to testosterone circulating in the blood and reduces the “free testosterone”. This reduction of free testosterone potentiates the likelihood of women exhibiting signs and symptoms of testosterone deficiency.

There is little or no effect on SHBG levels with standard estrogen patch therapy or estrogen gels and creams, due to the different dose form (transdermal delivery). SHBG levels only become raised when estrogen is swallowed and passed through the liver.

If a woman is using HRT or the Pill and experiencing a lowered sexual drive or unexplained lethargy and fatigue, it is advisable to change to a non-oral dosage form. This will reduce SHBG levels in her blood, freeing up testosterone. This increase in free testosterone should result in an improvement of symptoms. If not, then testosterone cream may be required.

## Non-Hormonal Drug Therapies

The use of certain medications are not directly linked to testosterone production, however, they are still an important consideration in determining causes of decreased sexual desire.



Medications which may interfere with sexual desire include:

MEDICATION	USE
SSRI's, tricyclics antidepressants	Depression
Oral estrogen	Oral contraceptive pill, HRT
Clonidine	Hot flushes
Medroxyprogesterone acetate (MPA)	Contraception, HRT
Spirolactone, cyproterone acetate	Hirsutism
Danazol	Endometriosis
Benzodiazepines	Anxiety, insomnia
Beta blockers	Hypertension
H <sub>2</sub> antagonists	Esophageal reflux
Ketoconazole	Vulvo-vaginal candidiasis
Gemfibrozol	Hyperlipidemia

Under no circumstances should patients change or cease taking medications without the consent of their doctor. If a patient is taking one or more of these medications and experiencing a lowered sexual desire, he or she should consult their medical practitioner.

## Signs and Symptoms of Testosterone Insufficiency

In 2002, many of the world's leading medical researchers and clinicians in the areas of endocrinology, gynecology and sexual health met at Princeton University, in New Jersey. They produced a document entitled "The Princeton Consensus Statement". This document provided a definitive classification of female androgen insufficiency. It made recommendations regarding diagnosis and assessment of androgen deficiency states in women.

The androgen-insufficient female was defined as having:

- Diminished sense of well-being, dysphoric mood and/or blunted motivation
- Persistent, unexplained fatigue
- Sexual function changes including decreased libido, sexual receptivity and pleasure
- (Potential) bone loss, decreased muscle strength and/or changes in cognition/memory

The Princeton Statement set these symptoms against a background of women having adequate estrogen levels, testosterone blood levels being in the lower range of normal healthy females and the ability to exclude other causes that could bring about their symptoms.

Typical symptoms of diminished testosterone levels include:

- Loss of sexual desire
- Unexplained tiredness and fatigue
- Mood changes
- Sleep disturbances
- Reduced motivation and
- Body shape changes

Since then the North American Menopause Society, The Endocrine Society, the Australasian Menopause Society and the International Menopause Society have all issued guidelines for medical practitioners

on the use of testosterone in women. This is despite the fact no FDA product has been approved.

Studies show in the United States approximately 600,000 hysterectomies are performed annually. Bilateral salpingo-oophorectomy (removal of both ovaries) is performed in conjunction with hysterectomy in about half of all women. Reasons for these additional oophorectomies may include prophylactic prevention of ovarian cancer, endometriosis or pelvic inflammatory disease.

The cost in terms of immediate onset of menopause, loss of sexual drive and potentially diminished quality of life is unknown.

Other women, for various reasons, have lower than normal testosterone production even without removal of the ovaries. Their symptoms are no different to those listed above.

Female sexual dysfunction (FSD) is the general medical term given to women who experience sexual difficulties including loss of sexual desire, lack of arousal and low libido.

### **FSD has four main sub-categories:**

- Hypoactive Sexual Desire Disorder (HSDD): defined as a lack or absence of feelings of sexual desire.
- Sexual Arousal Disorder (SAD)
- Sexual Pain Disorder and
- Orgasmic Disorder.

These issues are covered in greater detail in the booklet Understanding Low Libido in Women including access to an online Female Sexual Function Index self-assessment questionnaire.



This booklet can be downloaded from [www.hormonesolutions.com/lowlibido](http://www.hormonesolutions.com/lowlibido)

The answer to low libido for many women, especially those with HSDD, is the restoration of testosterone levels.

## Testosterone for Women – Treatment

The majority of female patients with testosterone deficiency exhibit reduced sexual drive and/or unexplained lethargy and fatigue. They may also experience altered mood.

Management requires a multidisciplinary, integrated approach. This should be co-ordinated by a suitably trained medical practitioner.

- Specific medical conditions such as iron deficiency, abnormal bleeding, diabetes, depression and thyroid disease should be addressed before considering hormonal therapies.
- Lifestyle changes such as exercise, smoking, alcohol intake and weight loss need to be reviewed.
- Vaginal lubricants provide symptomatic relief for vaginal dryness and dyspareunia (difficult or painful sexual intercourse). Localised estrogen pessaries, vaginal tablets, creams and gels can also be of great assistance.
- Pelvic floor physiotherapy will improve vaginal muscle tone, muscle associated with orgasm and in managing incontinence.
- Alteration of prescribed medications which may interfere with sexual function, if appropriate. Special attention should be paid to oral hormone replacement therapy (HRT), oral contraceptives and antidepressants. See the table under Non-Hormonal Therapies on page 13.



A medical practitioner's assessment of a patient must include:

## Medical History Including Sexual History

It is very important for your doctor to be skilled in discussing, understanding and managing problems associated with sexual matters. In terms of obtaining your sexual history, it is vital your doctor knows his or her limits. If your doctor has little or no training in sexual counseling a referral to a trained sex counselor is recommended.

A doctor should:

- not be judgemental due to his or her own sexual prejudices or "hang-ups"
- ensure the patient understands the principle of doctor-patient confidentiality
- be sensitive and optimistic when dealing with relationship issues
- encourage consultation with partner present
- allow extended time for consultations
- understand problems may not be revealed without specific inquiry
- understand sensitive and embarrassing issues may not be readily volunteered



## Examination

It is important a general “good female health” check be undertaken by your doctor.

Routine screening should include: a mammogram, a Pap smear, testing of cardiovascular parameters, a fasting blood glucose test, a serum thyroid stimulating hormone (TSH) level test, a full blood examination and iron studies.

Further investigations of specific medical disorders such as abnormal bleeding, breast lump(s), incontinence and osteoporosis are essential before any consideration of testosterone treatment.

A psychological evaluation of mood, well-being and sexual function may need to be conducted.

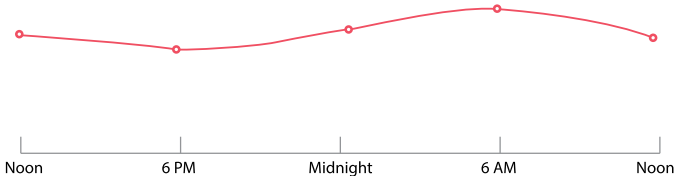
## Hormone Blood Testing

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

Testosterone secretion follows a diurnal rhythm in females. This means it rises and falls over a 24 hour period. Testosterone production occurs during the night and early morning with levels highest on waking. 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 hormone levels are at their highest. Individual variations in serum testosterone levels can occur due to time of day, medication usage, stress, illness, high alcohol intake or after recent surgery.

## Testosterone Circadian Rhythm in Women



■ Testosterone

[www.hormonesolutions.com](http://www.hormonesolutions.com)

The ovaries and adrenal glands 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).

Up to 99% of testosterone produced in the body is bound to SHBG. Once testosterone is bound to SHBG (bound testosterone), it is inactive.

Testosterone to which SHBG does not attach is biologically available testosterone. This is free to act on cells throughout the body (free testosterone or free T). Free testosterone is the vital component to measure when having a blood test.

Because SHBG has such a significant effect on testosterone, it is essential SHBG levels be considered when doing blood tests. High SHBG will result in free testosterone being low, hence the cause of lowered energy and libido.

Some doctors will measure only testosterone levels (called total testosterone) and 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.

In order to establish an accurate diagnosis for a patient, it is essential the testosterone component of most relevance be measured – the free testosterone. Free testosterone is best measured directly via a method called equilibrium dialysis. However, not many pathology laboratories have this specialized equipment. A more common and equally accurate method is via a mathematical calculation that takes into account SHBG levels. This is called the “calculated free testosterone” (cFT). This is the gold standard measurement when assessing testosterone status in women.

A good alternative to “free testosterone” measurement is the “free androgen index” or FAI. This is calculated by dividing the total testosterone level in the blood by the SHBG level, multiplied by 100. Pathology labs will automatically do this calculation and the result will be the FAI reading. Generally a FAI of less than two indicates there is very little free testosterone and is a likely cause of symptoms.

The table on the next page provides a summary of hormone blood test values.

PROFILE	TEST	NORMAL ADULT NON-PREGNANT FEMALE VALUE
Hormones	GH	0 to 8 ng/mL
	FSH	3 to 20 mIU/mL
	LH	<7 mIU/mL
	HCG	Negative unless pregnant
	Progesterone	<2 ng/mL before ovulation >5 ng/mL after ovulation
	Estradiol	Varies from 25 pg/mL (150 pmol/L) on Day 3 to 200 pg/mL (1200 pmol/L) around ovulation
	Prolactin	< 24 ng/mL
	Testosterone	28 to 80 ng/dL 1.0 – 2.8 nmol/L
	Free Testosterone	1.3 – 6.8 pg/mL 4.5 – 23.6 pmol/L
	Free Androgen Index (FAI)	2 – 6%
	SHBG	18 to 114 nmol/L

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

Free testosterone, or as a minimum the FAI, is essential in the assessment of testosterone deficiency as a cause of loss of libido, altered mood and decreased well-being. These measures are important regardless of menopausal status, age or ethnic background. Other factors such as pre-existing illnesses; physical, hormonal, psychological

or relationship issues; and mental health must be taken into account before considering testosterone treatment.

## Testosterone Treatment Options

The majority of patients with low testosterone levels exhibit reduced sexual drive, altered mood and unexplained lethargy and fatigue.

As discussed earlier, injections of testosterone and testosterone implants were designed for use in males and have been superseded by a product designed for delivering doses of testosterone appropriate for use in women.



This product is AndroFeme<sup>®</sup> 1% testosterone cream (Lawley Pharmaceuticals, Australia). AndroFeme<sup>®</sup> 1% testosterone cream treats low libido and low energy in women. The starting dose is 5mg (0.5mL) applied once daily to either the lower abdomen or upper outer thigh. It is important after three weeks use for blood testosterone levels to be measured, and if necessary, the dose adjusted. This is to ensure blood levels are maintained within the normal physiological range for women.

Additional details on testosterone cream for women can be found at [www.hormonesolutions.com/testosterone-women](http://www.hormonesolutions.com/testosterone-women)

## Risks of Testosterone Treatment in Women

Testosterone is recommended for use in women when ovarian function declines or, in particular, for young women who have had surgical removal of the ovaries. Ovarian function can decline from as early as the mid-thirties and is not necessarily directly related to menopause.

A full health check including testing blood testosterone levels should always be performed before using any testosterone replacement. It is essential a medical practitioner closely monitors testosterone therapy.

Provided blood testosterone levels are maintained within the normal range, side effects generally do not occur. Side effects may be induced when testosterone blood levels exceed the normal upper limits. This can happen with sustained high dose supplementation of testosterone.



Possible side effects of testosterone include the following:

- Nausea and vomiting
- Jaundice
- Joint swelling
- Increased body hair
- Deepening of the voice
- Increased acne

- Signs of virilization
- Weight gain
- Persistent headaches

It is very important to understand these side effects are extremely unlikely when doses are monitored and blood levels are kept within the normal ranges.

In general, testosterone supplementation should only be used when a woman's estrogen levels are adequate. However, post-menopausal women who are not taking an estrogen supplement may benefit from testosterone.

Osteoporosis is an area of women's health where testosterone has been shown to play an important role. A number of medical studies have strongly indicated the positive effect testosterone has on bone mineral density. Little has been done to examine how this effect translates into reduction of bone fractures.



## Testosterone for Women – Quick Q & A

**Q.** Why do women need testosterone?

**A.** In women, as with men, testosterone plays a crucial role in sexual motivation (libido), energy levels, mood and bone metabolism. Women produce testosterone from the ovaries and adrenal glands. When testosterone production declines, libido and energy levels often diminish. Supplementing small amounts of testosterone will restore blood levels to normal ranges, usually resolving symptoms.

**Q.** Is testosterone safe to use in women?

**A.** Yes, provided the dose used is appropriate for maintaining blood levels within normal ranges for women. The use of AndroFeme® 1% testosterone cream is only to replace the lack of natural testosterone production from the adrenal glands and ovaries.

**Q.** Will I grow hair, muscles or have voice changes using AndroFeme® 1% testosterone cream for women?

**A.** No, provided recommended doses are adhered to. Women using testosterone cream must have their blood testosterone checked regularly, especially upon starting testosterone treatment. This ensures the dose used is appropriate for the individual.

**Q.** How much and how often do I apply AndroFeme® 1% testosterone cream?

**A.** The cream is applied once daily to clean dry skin. It can be applied at any time of the day. The usual starting dose of



AndroFeme® 1% testosterone cream in women is 0.5mL (5 mg testosterone) via measured applicator, applied once daily to the lower abdomen or upper outer thigh.

A demonstration video of how to use the applicator is available at [www.hormonesolutions.com/video](http://www.hormonesolutions.com/video)

- Q.** How soon after starting the Lawley AndroFeme® 1% testosterone cream will my energy and libido improve?
- A.** Testosterone blood levels reach a “steady-state” after two weeks of once-daily use. Usually, energy levels improve within the first three to four weeks. Blood levels should be taken three to four weeks after commencement. An improved libido usually follows within four to six weeks after starting treatment.
- Q.** For how long can I continue to use testosterone cream?
- A.** Many women have used the AndroFeme® 1% testosterone cream continuously for over ten years. Clinical trials have been conducted with testosterone products in women for decades. Minimal side effects have been observed when the testosterone blood levels have been maintained within the normal range for women. It is important a blood test is conducted at least every six months while using testosterone cream to check levels remain within the normal limits for women.
- Q.** What safety checks do I need before starting AndroFeme® 1% testosterone cream?
- A.** Your doctor needs to conduct a general women’s health check including testosterone blood levels prior to starting testosterone treatment. Testosterone should not be used if you have breast cancer or if the health check shows any irregularities. These must be investigated fully first. If you have chronic liver or kidney disease, testosterone should only be used with strict medical supervision. Testosterone blood levels should be taken two to three weeks after starting treatment because of individual variation in skin absorption. If the blood testosterone level is elevated above the upper limit the dose can easily be adjusted downwards.

- Q.** If I stop using testosterone cream, how quickly will the testosterone be out of my system?
- A.** Once supplementation with AndroFeme® 1% testosterone cream is stopped, blood testosterone levels will fall to baseline levels within 72 hours. Pre-treatment symptoms will usually return with this decline in blood testosterone levels.
- Q.** Is the AndroFeme® 1% testosterone cream my only option for using testosterone?
- A.** There is only one listed pharmaceutical-grade testosterone product in the world available for use in women - AndroFeme® 1% testosterone cream.
- Q.** How long will a tube of testosterone cream last?
- A.** A single 50 mL tube of AndroFeme® will provide between 50 to 100 days of treatment depending upon the dose used. Using the recommended starting dose of 0.5mL, a tube will last 100 days.
- Q.** Where do I apply testosterone cream?
- A.** AndroFeme® 1% testosterone cream is applied to the skin of the lower torso or upper outer thigh. The testosterone is absorbed by the skin and passes into the blood. The cream is applied once daily. It is rubbed into the skin like a moisturizer. There should be no residual cream on the skin after about 60 seconds of massaging into the skin. The cream is white, odorless and non-staining.

## 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.

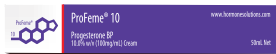
### AndroFeme® 1% testosterone cream for women



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



### ProFeme® 3.2% and 10% progesterone creams for women



## Our Mission Statement

Lawley Pharmaceuticals ([www.lawleypharm.com.au](http://www.lawleypharm.com.au)) 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.*

## Copyright Information

© Lawley Pharmaceuticals 2014

This publication is copyright. Other than for the purposes of and subject to the Copyright Act, no part of it may in any form or by any means (electronic, mechanical, microcopying, photocopying, recording or otherwise) be reproduced, stored in a retrieval system or transmitted without prior written permission.

All inquiries should be addressed to Lawley Pharmaceuticals.

This brochure is presented by

Lawley Pharmaceuticals

2/15A Harrogate St, West Leederville 6007, WA Australia

**T.** +61 (0)8 9388 0096

**F.** +61 (0)8 9388 0098

**E.** [info@hormonesolutions.com](mailto:info@hormonesolutions.com)

**W.** [www.hormonesolutions.com](http://www.hormonesolutions.com)

USA and Canada Toll free phone: 1-800-961-7813

Toll free fax: 1-800-961-7650

**LAWLEY**

Hormone Solutions