Step-by-Step Guide to Diagnosis and Treatment[1,2] of Male Hypogonadism with AndroForte® 5 Scrotal

This guide is to be used in conjunction with the full AndroFortee® 5 Product Information sheet[2].

LAWLEY

Alcohol-Free Scrotal Application

AndroForte® 5 is indicated for use as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.

Symptoms

- Mood changes (irritability, poor memory, low mood)
- Decreased muscle strength and lean body mass (decreased body fat)
- Osteoporosis (thinning of the bones)
- Decreased body hair
- Gynecomastia (enlarged breasts)
- Low energy
- Decreased libido and erectile quality
- Low semen volume

Medical History

- Undescended testes
- Testicular surgery
- Pubertal development or virilisation
- Fertility
- Genitourinary infection
- Coexistent illness (e.g. pituitary disease, thalassaemia, haemochromatosis).
- Sexual function (all men presenting with erectile dysfunction should be assessed for androgen deficiency, even though it is an uncommon cause)
- Drug use (medical or recreational)

Contraindications

Absolute Contraindications:

- Known or suspected cancer of the prostate or breast
- Haematocrit > 55%.

Relative Contraindications:

- Haematocrit > 52%
- Untreated sleep apnoea
- Severe urinary obstructive symptoms of benign prostatic hyperplasia (international prostate symptom score > 19)
- Advanced congestive heart failure.

Consideration:

Exogenous testosterone suppresses spermatogenesis in eugonadal men. Men with secondary hypogonadism who wish to preserve fertility should be managed using gonadotrophin therapy

Laboratory Assessment

At least two measurements of serum testosterone, LH and FSH (from samples collected on separate days) are required for diagnosis of androgen deficiency.

Serum total testosterone* (morning, fasting):

- Young men: (21-35 years) 10.4-30.1 nmol/l[3] ; (19-22 years) 7.4-28.0 nmol/l[4]
- Healthy older men (71-87 years), 6.6-26.7 nmol/l[5].

*Accurate serum testosterone measurements require mass spectrometry.
Values from immunoassays are less reliable.

Serum FSH reference range

- Young adult: (21-35 years), 1.2-9.5 IU/ml[3] ; (19-22 years), 1.3-12 IU/l[4].
- Older adult (74-84), mean 10.11, 95% confidence intervals 9.27-11.02 IU/l[6].

Serum LH reference ranges

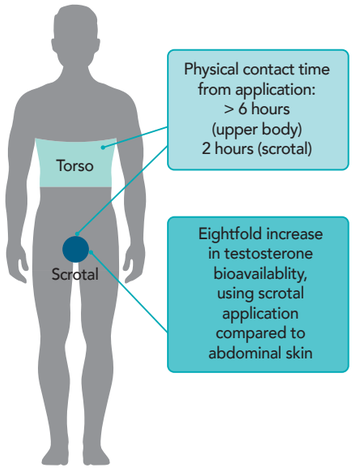
- Young adult: (21-35 years), 1.5-8.1 IU/l[7] ; (19-22 years), 5.1-18.7 IU/l[4].
- Older adult (74-78 years), median 4.1, interquartile range 3.0-6.1[7].
- Older adult (84-87 years), median 6.8, interquartile range 4.3-10.4[7].

PBS criteria requires men to be 40yrs+ and confirmed by serum testosterone below 6 nmol/l, or 6-15 nmol/l with LH 1.5 times higher than reference range (or above 14 IU/l).

Other Investigations

- Serum prolactin (for prolactinoma and macroadenoma)
- Iron studies and full blood count (for haemochromatosis and thalasaemia)
- Anterior pituitary function (for hypopituitarism and/or hyperfunctioning adenoma)
- Karyotyping (for suspected Klinefelter syndrome)
- Y chromosome microdeletion analysis
- Magnetic Resonance Imaging (for various hypothalamic or pituitary lesions).

Treatment



AndroForte® 5	5% (50mg/mL) testosterone cream	
Application site	**Scrotal (NEW)**	Torso
Starting Dose	**0.5mL (25mg)**	2mL (100mg)
Maximum Dose	**1mL (50mg)**	4mL (200mg)
Switch	**Topical - No washout required** **Injection - T levels at trough or return of symptoms**	
Packaging	**50mL tube** **100 days using** **0.5mL once daily**	50mL tube 25 days using 2mL once daily
Private script cost per month	**$31.87**	$127.46
PBS status and price per month	**PBS Authority** **General patient $9.00** **Concession $2.19**	non-PBS

Follow Up

Monitoring TRT

- Alleviation of a patient's leading symptom is the best clinical measure of effective management.
- Persistently elevated LH levels during TRT may indicate inadequate dosing.
- Periodic monitoring (1-2 year intervals) of bone mineral density may assist in monitoring TRT.
- Haematology profile should be assessed 3 months after initiating TRT and annually thereafter.
- Monitoring for prostate disease in men using TRT should occur as for eugonadal men of the same age.

Switching to Scrotal

- T gels cannot be applied to genital areas because high alcohol content, may cause scrotal irritation.[8]
- Injection - T levels at trough or return of symptoms
- Topical - No washout period required

Scrotal Dosing

- Recommended starting dose is 25mg (0.5mL)
- Titrate up or down by 0.25mL increments following serum blood test, if required.
- Two serum testosterone levels should be taken at 3 hours (peak) and 24 hours (trough) after the 15th day of starting treatment.
- Do not exceed 1mL (50mg) dose per day.
- The scrotum is not required to be shaved prior to application.

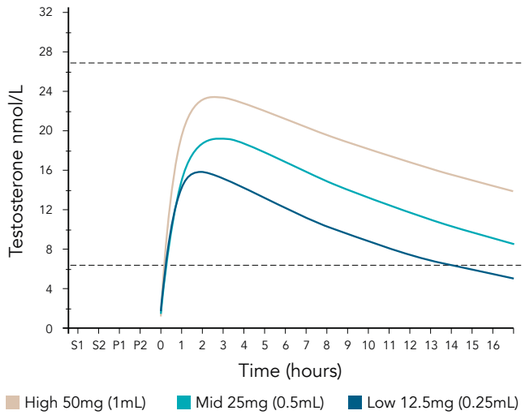
References: 1. www.andrologyaustralia.org. Clinical Resources for Health Professionals: Androgen Deficiency and Management Guide. Accessed July 2021. (abridged version with permission). 2. AndroForte 5 Product Information 3. Sikaris et al., 2005. Reproductive Hormone Reference Intervals for Healthy Fertile Young Men: Evaluation of Automated Platform Assays. The Journal of Clinical Endocrinology & Metabolism 4. Hart et al., 2015. Testicular function in a birth cohort of young men. Human Reproduction 5. Yeap et al., Reference Ranges and Determinants of Testosterone, Dihydrotestosterone, and Estradiol Levels Measured using Liquid Chromatography-Tandem Mass Spectrometry in a Population-Based Cohort of Older Men. The Journal of Clinical Endocrinology & Metabolism 6. Bjørnerem et al., 2004. Endogenous Sex Hormones in Relation to Age, Sex, Lifestyle Factors, and Chronic Diseases in a General Population: The Tromsø Study. The Journal of Clinical Endocrinology & Metabolism 7. Yeap et al., 2018. Progressive impairment of testicular endocrine function in ageing men: Testosterone and dihydrotestosterone decrease, and luteinizing hormone increases, in men transitioning from the 8th to 9th decades of life. Clinical Endocrinology. 8. Testogel Product Information. 9. Iyer R, Mok SF, Savkovic S, et al. Pharmacokinetics of testosterone cream applied to scrotal skin. 10. Feldman RJ J. Invest. Dermatol. 1967:48:181-183.

Why use AndroForte® 5 Scrotal?

Better Absorption

Eight-fold bioavailability

Peak at **3hrs of administration**[9]



Lower Dose Volume

One-tenth the volume superscript [2,8]

100 doses

@ 25mg (0.5mL) a day

Scrotal Dosing

Recommended starting dose is 25mg (0.5mL)

- Titrate up or down by 12.5mg (0.25mL) increments following serum blood test, if required.
- Two serum testosterone levels should be taken at 3 hours (peak) and 24 hours (trough) after the 15th day of starting treatment.
- Do not exceed 1mL (50mg) dose per day.
- The scrotum is not required to be shaved prior to application.

Switching to Scrotal

T gels cannot be applied to genital areas because high alcohol content, may cause scrotal irritation.[8]

Injection
T levels at trough or return of symptoms

Topical
No washout period required

PBS Information: Authority required for scrotal application.
Application to the torso is non-PBS. Refer to PBS Schedule for full information.

Please review full AndroForte® 5 Product Information before prescribing at www.lawleypharm.com.au/products

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Switch and save patients up to $550 each year.

PBS concessional cost per year: Testogel - $88.82. Reandron - $31.72. AndroForte® 5 Scrotal - $26.65. Reandron - AndroForte® 5 comparison (cost per year): PBS General $130.36 Private Rx $506.05 Patient saves $69.96 PBS General and $118.80 Private Rx.
* Price comparisons based upon: one month supply is 365 days; a 1 year supply is 365 days; pricing effective as published on PBS website 1st January 2023; all dosing according to the recommended starting dose as per the TGA approved Product Information; private Rx pricing using discount pharmacies pricing based on PBS dispensed price maximum quantity (DPMQ).

2021 AndroForte 5 scrotal cream — 6TH GEN

2015 AndroForte 5 torso cream — 5TH GEN

2005 Reandron LA injections — 4TH GEN

2004 Testogel gel — 3RD GEN

2002 Androderm patch

1985 Testoderm Scrotal patch
Testosterone **scrotal** patch licensed in Europe and USA — 2ND GEN

1975 Andriol oral capsules

1967

1958 Sustanon / Primoteston SA injections — 1ST GEN

1935 Testosterone isolated

Testosterone Cost Calculator

Calculate how much your patients will save.

All products.
All doses.
PBS and Private.

www.lawleypharm.com.au/testosterone_cost_calculator

History

Scrotal skin identified as most receptive to transdermal steroid absorption[6,10]

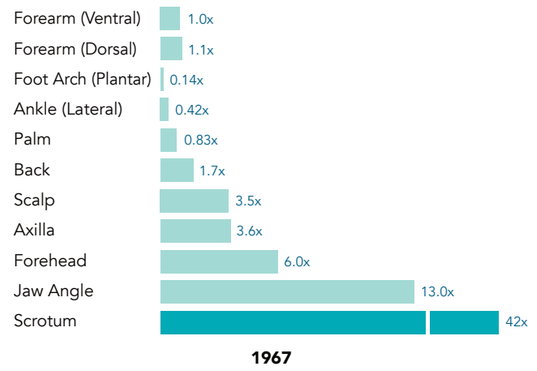

Fig 1. Total absorption of corticosteroid cream from different areas.[10]