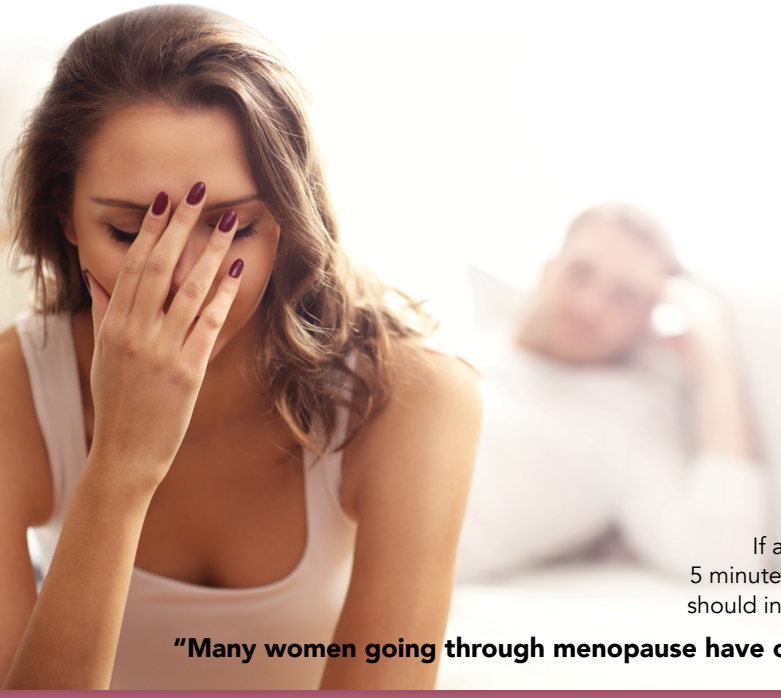
LAWLEY

TESTOSTERONE FOR WOMEN

LET'S TALK HSDD



Indication: The management of hypoactive sexual desire dysfunction (HSDD) in postmenopausal women.

1 in 3 women

(aged 40-64) will experience HSDD which can severely impair relationships, mental health, social functioning and overall QOL.[1,2,3]

If a woman does not spontaneously report a sexual problem in the first 5 minutes of a routine office visit (12% do begin the discussion), the provider should introduce the topic, as 36% of women then report sexual dysfunction.

"Many women going through menopause have concerns with sexual function; is this a concern for you?"

Why use AndroFeme® 1?

- **Available**
- **Effective**
- **Affordable**

2000 — AndroFeme® 1 licensed with WA Health and available in all WA pharmacies.

2014 — AndroFeme® 1 pivotal PK study[6]

2019 — T in Women pivotal meta-analysis[8]

2020 — AndroFeme® 1 TGA ARTG registration[10] — 1ST GEN

1999 — AndroFeme® 1 PK study[4]

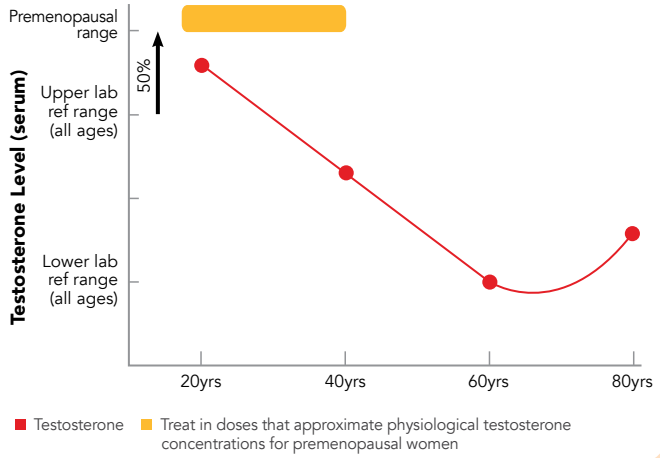
2007 — AndroFeme® 1 pivotal study[5]

2018 — ISSWSH - HSDD Process of Care[7]

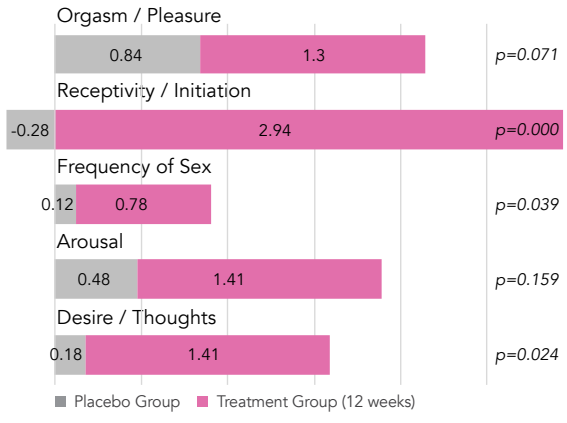
2019 — IMS Global Position Statement[9]

2021 — AndroFeme® 1 available Australia-wide

Testosterone Levels in Women[9,10,11,12]



Brief Index of Sexual Function for Women (BISF-W) subscale scores[5]



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Diagnosis

Screening

1. Menopause Checklist[13]
2. DSDS: Decreased Sexual Desire Screener[14]

Decreased Sexual Desire Screener (DSDS)
Patient MAY qualify for acquired, generalized HSDD if YES to Q 1-4 and NO to all factors in Q 5.
Patient MAY qualify for acquired, generalized HSDD if YES to Q 1-4 and YES to any factors in Q 5 if determined by clinical judgment*

*see reference 14

Modifiable Factors

Contributing Factors
- Menopausal symptoms
- Physical examination
- Psychological evaluation
- Medical conditions
- Medications

Gynaecology Factors
- Vaginal atrophy
- Dryness and/or pain

Sexual / Relationship Factors
- Relationship problems
- Partner's health
- Sexual assault / abuse

Serum – what to measure and why?

- It is recommended that serum testosterone monitoring be used as an aid to treatment rather than as the primary measure of efficacy.[10]
- No cut-off blood level can be used for any measured circulating testosterone to differentiate women with and without sexual dysfunction.[9]
- Serum testosterone concentrations **must not** be used as a treatment target.
- Attend the same laboratory for each blood test.[10]
- Baseline testosterone and sex hormone-binding globulin (SHBG) levels should be obtained prior to initiation of testosterone therapy and 3-6 weeks after therapy initiation.
- Measuring testosterone should be used for possibly overuse, but **must not** be used as the primary guide for patient management.

Total Testosterone	Measuring total testosterone as the main biomarker rather than 'free' testosterone, as evidence that 'free' testosterone is the biologically active testosterone fraction is lacking.	
SHBG	Testosterone binds to SHBG and bioavailability needs to be considered.	
	LOW	**HIGH**
	Be mindful of concurrent therapies that reduce SHBG. Tibolone Glucocorticoids	Review concurrent therapies to reduce SHBG to mid-range. e.g. oral oestrogen, thyroxine dose. Change to transdermal oestrogen and re-test SHBG in 12 weeks.

Treatment

The aim of treatment is the resolution of symptoms by administering testosterone in doses that approximate physiological testosterone concentrations in premenopausal women.[9]

AndroFeme® 1	1% testosterone cream
Application site	**Upper outer thigh or buttock**
Starting dose	**0.5mL (5mg) once daily**
Maximum dose	**1mL (10mg)**
Dose adjustment	**Titrate up or down by 0.25mL increments depending upon symptom response. See monitoring below.**
Pack size	**50mL tube** **100 days using 0.5mL once daily**
Private script	**$100 per tube ≈ $30 per month**
PBS status	**Not PBS listed**

Monitoring / Follow up

The primary indicator of efficacy is symptom improvement in sexual function as reported by each woman. Improvement is not immediate and generally onset takes 4-8 weeks; peaking at 12 weeks.[10]

Timeline	SHBG/Serum Testosterone	Efficacy/Safety review	Dose Modification (if required)
3-6 weeks	✓		✓
12 weeks	✓	✓	✓
6 months	✓	✓	
Morning blood sample to be taken prior to application of daily dose.			
Women with total testosterone concentrations greater than 50% above the upper limit of the **premenopausal reference range** for the assay being used should be advised to reduce the dose of the applied cream.			
Monitor dose and efficacy at 3 months and review 6 monthly. If no efficacy reported at 6 months, cease therapy.			

Therapy beyond 24 months should be an informed decision by physician and patient.

Safety

- It is recommended that if the serum testosterone concentration exceeds the upper limit of the **premenopausal range** of the assay being used that clinical evaluation is needed to screen for evidence of hyperandrogenism and a dose reduction considered. Typically serum T levels return to baseline 2-5 days post cessation of therapy.
- Patients should be made aware that long-term skin-to-skin contact particularly with children, can lead to adverse events including signs of virilisation.
- There is a lack of clinical trial safety data beyond 24 months.

PBS Information: Non PBS listed. Available nationally as a private prescription.

Please review full AndroFeme® 1 Product Information before prescribing at www.lawleypharm.com.au/products

References: **1.** Simon JA Climacteric 2018;5:415-427 **2.** Worsley R. J Sex Med. 2017 May; 14(5):675-686 **3.** Fooladi E. Climacteric 2014;17:674-681 **4.** Eden JA. AMS Congress, Adelaide 2000 **5.** El Hage G. Climacteric 2007;10:335-343 **6.** Fooladi E. Menopause 2015;22(1):44-49 **7.** Clayton A. Mayo Clin Proc. 2018;93(4):467-487 **8.** Islam R. Lancet Diab Endo 2019;7(10):754-766 **9.** Davis SR. 2019 JCEM;104(10):4660-4666 **10.** AndroFeme 1 PI **11.** Skiba M. 2019 JCEM;104(11);5382-5392 **12.** Davison S. JCEM 2005;90:3847-3853 **13.** Menopause Symptom Checklist **14.** Clayton 2013 J Sex Martial Ther. 39:132-143.

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