Hormonaly ACADEMY

EVIDENCE MONOGRAPH · FOR LICENSED CLINICIANS

Testosterone in Women

Pellets, injections, creams, gels, vaginal and beyond — the evidence, the formulations, and the law

An evidence-graded reference to testosterone therapy in women: the single evidence-based indication, how to measure and monitor, every route kept honest as approved, off-label or compounded, what the trials show, and the regulatory map across jurisdictions.

First edition · 2026



288.4 g/mol

C19H28O2

Fady Hannah-Shmouni, MD FRCPC
Endocrinologist and biochemical geneticist

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An authoritative reference for licensed clinicians. Educational content and a reference for clinical reasoning — not medical advice for any individual.

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How to use this book

How the chapters are built, what the evidence grades mean, and the limits of this reference.

HOW EACH CHAPTER IS BUILT

- A one-line statement of the clinical idea, then focused prose with inline citations numbered per chapter.
- Evidence chips mark the kind of data behind the chapter: human randomized trials, human cohorts, regulatory documents, mechanistic work or investigational products.
- A letter grade (A to D) rates the strength of evidence for the specific use described — not the elegance of the biology, and never the regulatory pathway. Chapters with mixed evidence carry no chapter grade; each section carries its own.
- KEY POINT panels carry the practical takeaway, CLINICAL PEARL panels practice tips, SAFETY panels the hazards, and STUDY PARAMETERS panels trial doses that are not dosing recommendations.

WHAT THE GRADES MEAN

GRADE	MEANING
A	Consistent randomized trials or meta-analyses for the stated indication.
B	A single high-quality trial, lower-quality trials, or strong observational data.
C	Limited data: mechanism plus small or uncontrolled studies.
D	Preclinical, in vitro, anecdotal or expert opinion only.

HOW TO USE THIS BOOK · CONTINUED

THREE PRODUCT CATEGORIES, ALWAYS KEPT APART

1. **Approved for women** in at least one jurisdiction — named with the regulator, the date and the label dose.
2. **Off-label** use of a product approved for men — regimens are given only as attributed guideline regimens.
3. **Compounded, unapproved or investigational** products — doses appear only as study parameters or as practice reported in observational data, never as recommendations.

UNITS

Testosterone is given in nmol/L first, then ng/dL (1 nmol/L = 28.84 ng/dL). SHBG is in nmol/L. Satisfying sexual events are reported per 4 weeks. Negative differences use a true minus sign.

SCOPE AND A DISCLAIMER

Testosterone has one indication in women supported by consistent randomized evidence — hypoactive sexual desire disorder in postmenopausal women — yet it is prescribed far more widely, often off-label, in compounded form or at supraphysiologic exposure. This book covers all of it: the physiology, the measurement, the disorders of androgen excess and deficiency, every formulation, every outcome studied and every population, with the regulatory and medicolegal context. It states where the evidence is strong, where it is weak and where it is absent.

This is educational content for licensed clinicians and a reference for clinical reasoning. It is not medical advice for any individual, does not establish a clinician–patient relationship, and does not replace specialist input or formal guidelines. Approvals, scheduling and compounding rules change quickly and differ by country. Core regulatory, labeling and guideline statements are current to 8 November 2026; explicitly identified post-cutoff updates verified through 14 November 2026 are listed in "About this edition." Verify current national sources, and confirm every citation against the primary literature, before acting.

HOW TO USE THIS BOOK · CONTINUED

BEFORE YOU START

In women the diagnosis is clinical. No serum testosterone concentration defines deficiency; testosterone is measured to exclude a high baseline and to keep therapy within the premenopausal physiological range.

Testosterone in women at a glance

The monograph's core positions on one page; each is developed, graded and referenced in the chapter shown.

TOPIC	SUMMARY
Indication	Hypoactive sexual desire disorder (HSDD) in postmenopausal women, after a biopsychosocial assessment, is the only use supported by consistent randomized evidence (house grade A; Chapters 6 and 18). Premenopausal HSDD is house grade C.
Effect size	Modest: about one additional satisfying sexual event per 4 weeks over placebo, with small gains in desire, arousal and orgasm and less distress (Chapter 18).
Diagnosis	Clinical. No serum testosterone concentration defines deficiency in women; low testosterone is not a diagnosis (Chapters 6 and 7).
Measurement	Total testosterone by LC-MS/MS where available, with SHBG; interpret against the laboratory's female reference interval, mainly to exclude a high baseline and supraphysiological exposure. Morning sampling and consistent timing for serial tests (Chapters 3–5).
Products for women	Testosterone 1% cream registered in Australia (2020) and authorised or approved in South Africa (2023), New Zealand (2025) and the United Kingdom (2025); the EU patch was withdrawn in 2012. No product is FDA-approved for women, as of 8 November 2026 (Chapter 26).

TESTOSTERONE IN WOMEN AT A GLANCE · CONTINUED

TOPIC	SUMMARY
Dosing principle	Keep concentrations within the physiological premenopausal range, never above it. Off-label use of male transdermal products is limited to attributed guideline regimens (Chapters 10 and 11).
Pellets, injections, oral, compounded	Not recommended by the major guidelines: unadjustable or supraphysiological exposure, or unverified quality, without randomized HSDD evidence (Chapters 12, 13, 15 and 17).
Vaginal testosterone	Small trials for genitourinary symptoms, including aromatase-inhibitor users (house grade B for that use; Chapter 14).
Monitoring	Baseline total testosterone and SHBG, a repeat at 3–6 weeks and after dose changes, then about every 6 months; stop if there is no meaningful benefit by 6 months (Chapter 21).
Not established	Wellbeing, mood, cognition, energy, bone and muscle at physiological doses; long-term breast and cardiovascular safety (Chapters 19 and 20).

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