OCW WP 055 / V1.0 / 4 NOV 2026

PATIENT GUIDE

Testosterone therapy *for men*

Testosterone replacement is FDA approved for men whose low testosterone has a medical cause. We cover how the diagnosis is made, what the large trials found, and how injections and pellets work.

COMPOUND	CLASS	FORMS	STATUS	SOURCES
Testosterone	Androgen, CIII	Injection, pellet	FDA approved	30 · PMID linked

§ 01

Overview

Testosterone is the main male sex hormone. When the testes, or the glands in the brain that control them, stop working properly, levels fall, and men may notice lower sex drive, fewer morning erections, weaker erections, less vigor and changes in mood.[1] [2] Replacing testosterone in men with a confirmed deficiency is an FDA approved treatment, and over the past decade two large programs of placebo controlled trials, the Testosterone Trials and TRAVERSE, have answered many of the questions men ask about its benefits and its effect on the heart.[18] [3] [4]

OC Wellness offers testosterone as injections into the muscle given in the clinic, through a monthly men's hormone program, and as small pellets placed under the skin. Every number here comes from a published trial, a society guideline or the FDA label, with sources listed at the end.

300	**The AUA cut off, in ng/dL.** The American Urological Association uses a total testosterone below 300 ng/dL, found on two early morning tests on separate occasions, together with symptoms or signs, to support the diagnosis.[1]
7.0%	**Heart attack, stroke or cardiovascular death in TRAVERSE.** Among 5,246 men aged 45 to 80 with heart disease or high heart risk, these events occurred in 7.0 percent on testosterone gel and 7.3 percent on placebo.[4]
65%	**Had no sperm by six months.** In a World Health Organization study, 271 healthy men were given 200 mg of testosterone enanthate weekly; by six months, 65 percent had no sperm in their semen. Sperm returned after the injections stopped.[5]
54%	**The hematocrit that calls for action.** Testosterone raises the red blood cell count. The AUA advises that a hematocrit of 54 percent or higher during treatment warrants intervention.[19]

§ 02

What testosterone is

Testosterone is a steroid hormone made mainly by the testes. It builds and maintains male characteristics, supports sex drive, helps maintain muscle and bone, and stimulates the production of red blood cells.[18] [6]

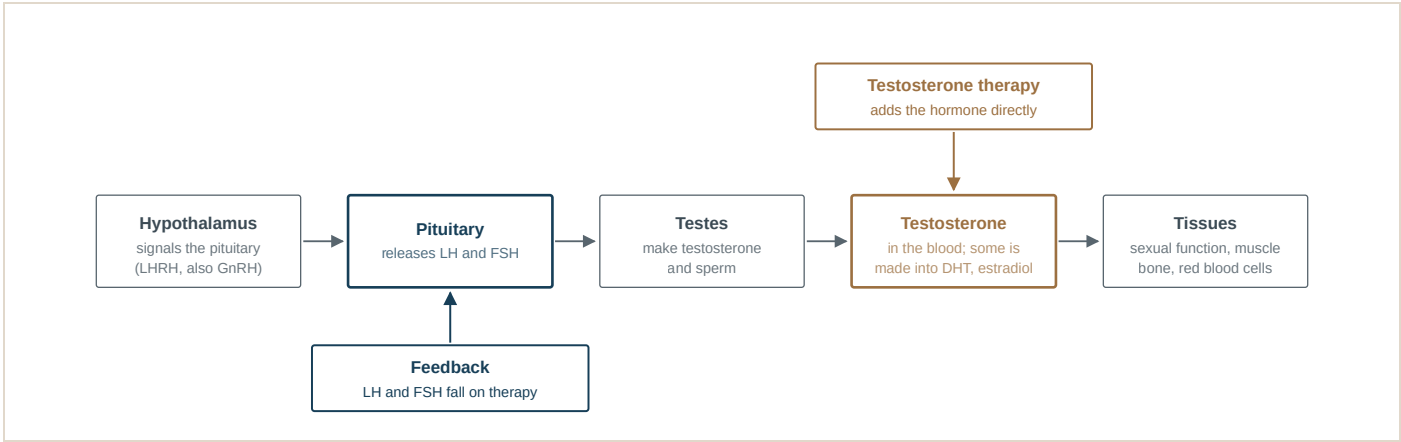
The medicines described here contain testosterone itself. For injection, testosterone is joined to a fatty acid (an ester), either cypionate or enanthate, and dissolved in oil, so it is released slowly from the muscle and then freed in the body.[18] [20] Pellets are small cylinders of crystalline testosterone, 3.2 mm across and about 9 mm long, that dissolve slowly under the skin.[21]

TESTOSTERONE AT A GLANCE	
Name	Testosterone
Products	Testosterone cypionate injection (Depo Testosterone and generics), testosterone enanthate injection, and testosterone pellets (Testopel)[18] [20] [21]
Structure	A steroid hormone; the injections carry it as a cypionate or enanthate ester in oil[18] [20]
Origin	The same hormone the testes make; the ester is removed in the body to release free testosterone[20]
Class	Androgen; a Schedule III controlled substance[18]
How it is given	Injection deep into the buttock muscle every 2 to 4 weeks, or pellets under the skin every 3 to 6 months[18] [20] [21]

§ 03

How testosterone works

Testosterone production runs on a feedback loop. The hypothalamus in the brain signals the pituitary gland, and the pituitary releases two hormones, luteinizing hormone (LH) and follicle stimulating hormone (FSH). LH drives the testes to make testosterone, and FSH supports sperm production.[18] In many tissues testosterone works after it is converted to dihydrotestosterone (DHT), which binds to receptors inside the cell and switches on the genes responsible for its effects.[18] Some testosterone is also converted to estradiol, which carries part of its effect.[6]



Testosterone therapy adds the hormone in the blood, and the body responds by turning down its own production. The pituitary senses the higher level and releases less LH, and at larger doses less FSH, so the testes make less testosterone and fewer sperm.[18] In tissues, some testosterone acts after conversion to DHT and some after conversion to estradiol.[6]

One study showed how the two conversions share the work. Researchers switched off natural hormone production in 400 healthy men aged 20 to 50 and replaced testosterone at different doses for 16 weeks, in some men also blocking its conversion to estradiol. Loss of androgen accounted for the falls in lean mass, muscle size and strength, loss of estrogen mainly accounted for the gain in body fat, and both contributed to the decline in sexual function.[6]

Testosterone given as a medicine sends the same feedback signal as the body's own hormone, so the pituitary releases less LH. The testes then make less testosterone of their own, and at larger doses sperm production is suppressed as FSH falls too.[18]

KEY POINT

Testosterone therapy replaces the hormone from outside, and while it is taken the body's own production is turned down.[18] Sperm counts usually fall as a result, and after treatment stops it takes months for sperm production to recover.[5][7] For this reason both the AUA and the Endocrine Society advise against starting it in men who are trying to conceive or planning fertility in the near term.[1][8]

§ 04

What the research shows

Two coordinated sets of randomized, double blind, placebo controlled trials anchor the evidence. The Testosterone Trials (TTrials) treated 790 men aged 65 or older with testosterone below 275 ng/dL and symptoms, for one year.[3] TRAVERSE enrolled 5,246 men aged 45 to 80 with symptoms, two fasting testosterone levels below 300 ng/dL, and heart disease or a high risk of it, and followed them for a mean of 33 months.[4] Both trials used a daily testosterone gel, so injections and pellets were not tested directly.

What the evidence supports

Sexual desire and activity improve. In the TTrials, testosterone significantly increased sexual activity, sexual desire and erectile function.[3] In TRAVERSE, among 1,161 men with low libido, testosterone improved sexual activity, sexual desire and symptoms of low testosterone over two years, although erectile function did not improve compared with placebo.[9]

Anemia often corrects. In the TTrials, among men with anemia that had no known cause, hemoglobin rose by 1.0 g/dL or more in 54 percent on testosterone and 15 percent on placebo, and 58.3 percent were no longer anemic at 12 months, compared with 22.2 percent.[10] In TRAVERSE, anemia had corrected at 12 months in 45.0 percent of men on testosterone and 33.9 percent on placebo.[11]

Bone density rises. In the TTrials Bone Trial of 211 men, density of the spongy bone of the spine rose by 7.5 percent in a year on testosterone and 0.8 percent on placebo, with a matching rise in estimated bone strength.[12] Mood also improved slightly, with lower severity of depressive symptoms.[3]

Heart attacks and strokes did not increase. In TRAVERSE, the combined rate of cardiovascular death, heart attack and stroke was 7.0 percent on testosterone and 7.3 percent on placebo (hazard ratio 0.96), which met the trial's test for safety. Atrial fibrillation, acute kidney injury and pulmonary embolism were more frequent on testosterone.[4]

What is not yet known

Testosterone did not improve energy (vitality) in the TTrials. Walking distance did not improve in men with slow walking who were enrolled for that question, though across all participants 20.5 percent on testosterone and 12.6 percent on placebo added at least 50 m to a six minute walk.[3] Memory and other thinking skills did not improve in 493 men with age associated memory complaints.[13] Fractures were not prevented despite the gain in bone density: in TRAVERSE they occurred in 3.50 percent on testosterone and 2.46 percent on placebo over a median of 3.19 years.[14] The AUA tells patients that the evidence is inconclusive on energy, fatigue, cognitive function, diabetes measures, cholesterol and quality of life.[1]

In the TTrials cardiovascular substudy, noncalcified plaque in the heart arteries grew more on testosterone than on placebo (an estimated difference of 41 mm^3 in 138 men), with no heart events in either group; its clinical meaning is unclear.[15] Trials of the size of TRAVERSE have not been run with injections or pellets, which give different blood levels from a daily gel.[8]

MAJOR HUMAN TRIALS All randomized, double blind and placebo controlled, using daily testosterone gel.

STUDY	N	WHO AND HOW	MAIN FINDING
TTrials 2016[3]	790	Men 65 or older, testosterone below 275 ng/dL, one year	More sexual activity, desire and erectile function; slightly better mood; no gain in energy
TTrials Anemia 2017[10]	126	TTrials men with anemia	Unexplained anemia: hemoglobin up 1.0 g/dL or more in 54 vs 15 percent
TTrials Bone 2017[12]	211	Spine and hip density by CT	Spine trabecular density up 7.5 vs 0.8 percent
TTrials Cognitive 2017[13]	493	Age associated memory impairment	No improvement in memory or other cognitive tests
TTrials Cardiovascular 2017[15]	138	Coronary CT angiography	Greater growth of noncalcified plaque; no heart events
TRAVERSE 2023[4]	5,246	Men 45 to 80, heart disease or high risk, testosterone below 300 ng/dL	Major heart events 7.0 vs 7.3 percent; more atrial fibrillation, kidney injury and pulmonary embolism
TRAVERSE Sexual Function 2024[9]	1,161	Men with low libido, two years	Better sexual activity, desire and symptoms; erectile function unchanged
TRAVERSE Anemia 2023[11]	815	Men with anemia at entry	Anemia corrected at 12 months in 45.0 vs 33.9 percent
TRAVERSE Fractures 2024[14]	5,204	Adjudicated clinical fractures	3.50 vs 2.46 percent; no reduction in fractures
TRAVERSE Prostate 2023[16]	5,204	Men with PSA above 3.0 ng/mL excluded	High grade prostate cancer 0.19 vs 0.12 percent, not significantly different

SUMMARY

For men with a confirmed deficiency, testosterone improves sexual desire and activity, corrects many cases of anemia, raises bone density and lifts mood slightly, and TRAVERSE found no increase in heart attacks or strokes over about three years. It did not improve energy or memory or lower fracture risk. It raises the red blood cell count and suppresses sperm production, so monitoring and a decision about fertility belong at the start.

§ 05

How testosterone is given

Each FDA label asks that the diagnosis be confirmed first, with testosterone measured in the morning on at least two separate days and found below the normal range.[18] [20] [21] The doses below are the ranges stated in each label, and within them the dose is adjusted to the man's response and to any side effects.[18] The AUA advises adjusting treatment to reach a total testosterone in the middle third of the normal range, and the Endocrine Society advises aiming for the middle of the normal range.[1] [8] FDA approved gels, patches, a buccal system, oral capsules and other injections also exist but are not covered here.[22]

Injection into the muscle

Testosterone cypionate and testosterone enanthate are injected deep into the gluteal (buttock) muscle, and neither may be given into a vein.[18] [20] Both labels give a replacement dose for men with hypogonadism of 50 to 400 mg every 2 to 4 weeks.[18] [20] The enanthate label adds that total doses above 400 mg a month are not required and that injections more often than every two weeks are rarely indicated.[20] Injected testosterone cypionate has a half life of about eight days.[18]

After each injection, blood testosterone rises above the normal range and then declines gradually, reaching the low range by the end of the dosing interval, and these peaks and troughs may affect how a man feels.[8] Injections of cypionate or enanthate also raise the hematocrit more than a skin patch does (see §07).[17]

Pellets under the skin

Each Testopel pellet contains 75 mg of testosterone. The label's dosage guideline for replacement is 150 mg to 450 mg under the skin every 3 to 6 months, which is 2 to 6 pellets.[21] About one third of the testosterone is absorbed in the first month, one fourth in the second and one sixth in the third, and the effect ordinarily lasts three to four months, sometimes as long as six.[21]

The label notes that pellets are much less flexible for adjusting the dose than injections, and that if a complication meant testosterone had to be stopped, the pellets would have to be removed.[21]

The monthly men's hormone program

OC Wellness also provides testosterone through a monthly men's hormone program. Your physician will explain which form of testosterone it uses in your case and how your treatment is scheduled. The label doses above, and the monitoring the guidelines describe in §08, apply to every form.

COMPARING THE OPTIONS

	INJECTION INTO THE MUSCLE	PELLETS UNDER THE SKIN
How often (label)	Every 2 to 4 weeks[18][20]	Every 3 to 6 months[21]
Blood levels	Above normal after the injection, low by the end of the interval[8]	Released over months, most in the first month[21]
Adjusting the dose	Adjusted to response at each injection[18]	Much less flexible; stopping requires removal[21]
Site problems	Pain and inflammation at the injection site[18][20]	Infection or pellet extrusion, mostly in the first month[21]
FDA approved product	YES	YES (TESTOPEL)

§ 06

What to expect

The first months. In the TTrials, treatment raised testosterone to the middle of the normal range for men aged 19 to 40.[3] In TRAVERSE the gain in sexual activity was present at 6 months and held at 12 and 24 months.[9] Energy did not improve in the trials.[3] If testosterone reaches the normal range but symptoms or signs have not improved after three to six months, the AUA advises discussing stopping treatment.[1]

With injections. Some soreness where the needle went in is common, and the labels list inflammation and pain at the injection site.[18][20] With enanthate there have been rare reports of a passing urge to cough, coughing fits or difficulty breathing immediately after the injection.[20]

With pellets. In studies summarized by the AUA, bruising (32 to 36 percent), pain (28 to 29 percent), tenderness (20 to 32 percent) and swelling (16 to 18 percent) at the site were mild and resolved by four months.[19] Infection or a pellet working its way out (extrusion) can happen at any time, but most reported cases occurred within the first month.[21]

DURING TREATMENT

- Report erections that are too frequent or will not go away, nausea, vomiting, changes in skin color, or ankle swelling, as the labels ask.[18] [20]
- Leg pain, swelling, warmth or redness, or sudden shortness of breath, needs urgent attention, because blood clots have been reported with testosterone products.[18]
- After pellets, report redness, drainage, increasing pain or a pellet coming through the skin.[21]

§ 07

Safety

The labels for testosterone cypionate, testosterone enanthate and Testopel carry no boxed warning and share the warnings below.[18] [20] [21]

- **Blood pressure.** Each label states: "Testosterone can increase blood pressure which can increase cardiovascular (CV) risk over time." The labels ask for blood pressure to be checked periodically, especially in men with hypertension, and do not recommend testosterone for uncontrolled hypertension.[18] [20] [21] In TRAVERSE, systolic pressure rose by a mean of 1.5 mm Hg more on testosterone gel than on placebo by 36 months.[23]
- **Blood clots.** There have been postmarketing reports of deep vein thrombosis and pulmonary embolism with testosterone products, and treatment is stopped if a clot is suspected.[18] [20] [21]
- **Heart events.** These three labels still state that randomized trials and epidemiologic studies have been inconclusive, that some studies but not all reported an increased risk of heart attack, stroke and cardiovascular death, and that patients should be informed of this possible risk.[18] [20] [21] TRAVERSE has since reported 7.0 percent with testosterone and 7.3 percent with placebo,[4] and in February 2025 the FDA asked that its results be added to the labeling of all testosterone products.[22]
- **Abuse and dependence.** The labels warn that abuse, typically at doses higher than recommended and with other anabolic steroids, can lead to serious cardiovascular and psychiatric reactions; dependence at approved doses for approved indications has not been documented.[18] [20] [21]
- **Other warnings.** Fluid retention in men with heart, kidney or liver disease; breast enlargement; acne; prostate enlargement in older men; liver problems with prolonged high doses.[18] [20]

EVENTS MORE FREQUENT ON TESTOSTERONE IN TRAVERSE Percent of men on testosterone gel or placebo over a mean of 33 months, from the FDA label of the gel used in the trial and the trial reports.[23] [16]

EVENT	TESTOSTERONE	PLACEBO
Heart attack, stroke or cardiovascular death (for comparison)	7.0%	7.3%
Nonfatal heart rhythm problems needing treatment	5.2%	3.3%
Atrial fibrillation	3.5%	2.4%
Bone fracture	3.5%	2.5%
Acute kidney injury	2.3%	1.5%
Blood clots in veins (all)	1.7%	1.2%
Pulmonary embolism	0.9%	0.5%
High grade prostate cancer	0.19%	0.12%

Red blood cells and hematocrit

Testosterone stimulates red blood cell production, and the labels list polycythemia, an excess of red cells, and advise checking hemoglobin and hematocrit periodically.[18] A systematic review and network meta analysis of 29 placebo controlled trials in 3,393 men found that every form raised the mean hematocrit, and injections of cypionate or enanthate raised it by 4.0 percentage points against placebo.[17] The AUA advises measuring hemoglobin and hematocrit before treatment, considering withholding testosterone if the hematocrit is above 50 percent until the cause is explained, and intervening if it reaches 54 percent or more during treatment, with dose adjustment the first step when testosterone levels are high.[1 19]

Prostate

The current labels list known or suspected prostate cancer as a reason not to use testosterone.[18 20 21] In TRAVERSE, which excluded men with a PSA above 3.0 ng/mL, high grade prostate cancer was diagnosed in 0.19 percent of men on testosterone and 0.12 percent on placebo, a difference that was not significant, while PSA rose more on testosterone.[16] The AUA advises measuring PSA before treatment in men over 40, and the Endocrine Society recommends a urology consultation for a confirmed PSA rise of more than 1.4 ng/mL above baseline, a confirmed PSA above 4.0 ng/mL, or an abnormality found on rectal examination.[1 8]

Fertility

The labels note that a low sperm count may occur after prolonged use or high doses.[18] In the WHO study, after the weekly injections ended, the median time for sperm to recover to 20 million per mL was 3.7 months.[5] An analysis of 1,549 men aged 18 to 51 in 30 studies found recovery to that level in 67 percent within 6 months, 90 percent within 12 months and 100 percent within 24 months, more slowly after longer treatment and longer acting preparations.[7] Men who want children in the future should have a reproductive evaluation before treatment.[1]

TELL YOUR PHYSICIAN BEFORE STARTING IF ANY OF THESE APPLY

- You are trying to conceive, or would like children in the near future.[1 8]
- You have had breast or prostate cancer, a prostate lump, a raised PSA, or severe urinary symptoms.[8 18]
- You have a high hematocrit, or untreated severe obstructive sleep apnea.[8]
- You have had a heart attack or stroke in the last six months, or have heart failure or blood pressure that is not controlled.[8 18]
- You have had a blood clot or have an inherited tendency to clot, or you have serious heart, liver or kidney disease.[8 18]
- You take a blood thinner, insulin or other diabetes medicines, or any other prescription, over the counter product or supplement. Please bring the full list.[18 20]

The TTrials lasted one year and TRAVERSE followed men for a mean of 33 months.[3 4] Trials of a similar size covering many years of continuous use, or testing injections and pellets specifically, have not been published.

§ 08

Is this right for you

Testosterone therapy suits men who have symptoms and a confirmed low level. The AUA makes the diagnosis only when a man has a total testosterone below 300 ng/dL on two early morning tests taken on separate occasions, combined with symptoms or signs.[1] The Endocrine Society recommends diagnosing hypogonadism only in men with symptoms and signs

and unequivocally and consistently low testosterone, measured fasting in the morning with an accurate assay and repeated to confirm. With assays certified by the Centers for Disease Control and Prevention, it gives the lower limit of normal in healthy nonobese young men as 264 ng/dL. [8]

Before we begin

- [ ] A review of your medical history, symptoms, current medications and supplements, and your plans for having children
- [ ] Blood pressure, weight and an examination, so we have a clear starting point
- [ ] Baseline bloodwork of the kind the guidelines describe: morning testosterone on two occasions, LH, hemoglobin and hematocrit, and PSA for men over 40 [1]
- [ ] A written note of your goals, so we can judge progress together

Finding the cause comes first. The AUA advises measuring LH in men with low testosterone, and prolactin when LH is low or low normal, and the Endocrine Society recommends further evaluation to find the cause of the deficiency. [1] [8] The AUA counsels lifestyle changes for every man with testosterone deficiency. [1]

Reviewing your progress

The AUA advises a first testosterone level two to four weeks after starting, depending on the form, then testosterone every 6 to 12 months, and hematocrit every 6 to 12 months or sooner, depending on earlier values, to keep it below 54 percent. [1] [19] The Endocrine Society's plan covers symptoms, side effects and adherence, testosterone and hematocrit levels, and prostate cancer risk during the first year. [8] Your physician will set your own schedule, and you are welcome to stop at any time.

> **QUESTIONS TO ASK YOUR PHYSICIAN**
>
> What is causing my low testosterone, and has it been looked for? Would injections or pellets suit me better? What will treatment mean for my fertility? Which blood tests will we check, and when? What would make you recommend stopping?

§ 09

Regulatory status

Testosterone cypionate injection, testosterone enanthate injection and Testopel pellets are FDA approved for replacement therapy in men with conditions in which the body makes too little or no testosterone of its own: primary hypogonadism, in which the testes fail, and hypogonadotropic hypogonadism, in which the pituitary or hypothalamus fails, for example after a tumor, trauma or radiation. [18] [20] [21] The FDA states that none is approved for men with low testosterone who lack an associated medical condition. [24]

In March 2015 the FDA urged caution in using testosterone for low testosterone due to aging, [22] and the current labels for these three products state that safety and efficacy in men with age related hypogonadism (also called late onset hypogonadism) have not been established. [18] [20] [21] In June 2026 the FDA asked manufacturers to remove that limitation and to narrow the prostate cancer contraindication to metastatic prostate cancer; these are requested changes, and as of 4 November 2026 the labels described here had not yet been revised. [25] [24] [18] Prescribing testosterone for low testosterone due to aging without an associated condition is therefore off label at present. A physician may prescribe a medicine off label when it suits the patient, and your physician will discuss this with you if it applies.

Testosterone is a Schedule III controlled substance under the Controlled Substances Act.[18] Compounded testosterone products, including pellets made by compounding pharmacies, are not FDA approved, and the FDA does not verify their safety, effectiveness or quality before they are sold.[26] The AUA recommends commercially manufactured products when possible.[1]

For athletes, testosterone is on the World Anti Doping Agency Prohibited List under S1, anabolic agents, prohibited at all times, in and out of competition.[27] A tested athlete needs an approved therapeutic use exemption. The U.S. Anti Doping Agency requires an unequivocal organic cause in every case, states that an exemption is extremely unlikely for functional hypogonadism, and does not accept use as an anti aging medicine as a justification.[28]

If you would like details about the preparation used in your treatment, please ask.

§ 10

Common questions

Is testosterone therapy FDA approved?

Testosterone cypionate and enanthate injections and Testopel pellets are FDA approved for men whose low testosterone is caused by failure of the testes, the pituitary or the hypothalamus.[18][20][21] Compounded testosterone is not FDA approved.[26] If you would like details about the preparation used in your treatment, please ask.

My testosterone is low and I am getting older. Can I be treated?

The current labels state that safety and efficacy in age related hypogonadism have not been established, so treatment for that reason alone is off label for now.[18] The FDA asked in June 2026 for that limitation to be removed, though the labels have not yet changed.[25][24] For men 65 or older, the Endocrine Society suggests deciding on an individual basis.[8]

Is it safe for my heart?

In TRAVERSE, among men with heart disease or high heart risk, heart attack, stroke or cardiovascular death occurred in 7.0 percent on testosterone and 7.3 percent on placebo.[4] Atrial fibrillation, acute kidney injury and pulmonary embolism were more frequent on testosterone, and blood pressure rose slightly.[4][23]

Will it affect my fertility?

Testosterone therapy lowers the pituitary signals that drive sperm production, and in a WHO study 65 percent of healthy men on weekly enanthate injections had no sperm by six months.[18][5] Sperm usually returned after stopping, in most men within a year.[7] The AUA advises that testosterone should not be prescribed to men who are trying to conceive.[1]

Does testosterone cause prostate cancer?

In TRAVERSE, high grade prostate cancer occurred in 0.19 percent of men on testosterone and 0.12 percent on placebo, which was not a significant difference, though PSA rose more on testosterone.[16] Men with known or suspected prostate cancer should not use it under the current labels, and the guidelines call for PSA checks.[18][1][8]

I compete in sport. Can I use testosterone?

Testosterone is prohibited at all times under the World Anti Doping Agency list, so a tested athlete needs an approved therapeutic use exemption.[27] The U.S. Anti Doping Agency grants one only for a clearly organic cause of low testosterone, and not for anti aging use.[28]

Where is a compounded medicine made, and who oversees it?

Federal law sets out two kinds of compounding. Under section 503A, a state licensed pharmacy or physician prepares a medicine for one patient against that patient's own prescription, and the state board of pharmacy carries the day to day oversight while the FDA inspects for cause and on surveillance.[26] Under section 503B, an outsourcing facility registers with the FDA, works to federal manufacturing quality standards, reports adverse events and the products it makes to the agency, and is inspected by the FDA on a risk based schedule; it may also supply a clinic directly rather than for one named patient.[29] We use both kinds, and which one prepares your medicine depends on the preparation.

Is a compounded medicine the same as an FDA approved one?

No, and the difference matters. An approved product, which here means the injections or Testopel, is the first choice whenever one fits your situation.[26] What a prescription from a licensed pharmacy or a registered outsourcing facility does give you is a named prescriber, a facility answerable to a state board or to the FDA, ingredients that meet federal requirements, and a route for reporting a problem. A vial bought online and labelled for research use only has none of that, and the FDA treats those products as unapproved new drugs when they are meant for people, so please do not use one.[30]

References

Sources cited in this guide

1 **Mulhall JP, et al.** Evaluation and Management of Testosterone Deficiency: AUA Guideline.
J Urol. 2018;200(2):423 to 432. PMID 29601923

2 **Wu FC, et al.** Identification of late onset hypogonadism in middle aged and elderly men.
N Engl J Med. 2010;363(2):123 to 135. PMID 20554979

3 **Snyder PJ, et al.** Effects of Testosterone Treatment in Older Men.
N Engl J Med. 2016;374(7):611 to 624. PMID 26886521

4 **Lincoff AM, et al.** Cardiovascular Safety of Testosterone Replacement Therapy.
N Engl J Med. 2023;389(2):107 to 117. PMID 37326322

5 **World Health Organization Task Force on Methods for the Regulation of Male Fertility.** Contraceptive efficacy of testosterone induced azoospermia in normal men.
Lancet. 1990;336(8721):955 to 959. PMID 1977002

6 **Finkelstein JS, et al.** Gonadal steroids and body composition, strength, and sexual function in men.
N Engl J Med. 2013;369(11):1011 to 1022. PMID 24024838

7 **Liu PY, et al.** Rate, extent, and modifiers of spermatogenic recovery after hormonal male contraception: an integrated analysis.
Lancet. 2006;367(9520):1412 to 1420. PMID 16650651

8 **Bhasin S, et al.** Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline.
J Clin Endocrinol Metab. 2018;103(5):1715 to 1744. PMID 29562364

9 **Pencina KM, et al.** Effect of Testosterone Replacement Therapy on Sexual Function and Hypogonadal Symptoms in Men with Hypogonadism.
J Clin Endocrinol Metab. 2024;109(2):569 to 580. PMID 37589949

10 **Roy CN, et al.** Association of Testosterone Levels With Anemia in Older Men: A Controlled Clinical Trial.
JAMA Intern Med. 2017;177(4):480 to 490. PMID 28241237

11 **Pencina KM, et al.** Efficacy of Testosterone Replacement Therapy in Correcting Anemia in Men With Hypogonadism: A Randomized Clinical Trial.
JAMA Netw Open. 2023;6(10):e2340030. PMID 37889486

12 **Snyder PJ, et al.** Effect of Testosterone Treatment on Volumetric Bone Density and Strength in Older Men With Low Testosterone: A Controlled Clinical Trial.
JAMA Intern Med. 2017;177(4):471 to 479. PMID 28241231

13 **Resnick SM, et al.** Testosterone Treatment and Cognitive Function in Older Men With Low Testosterone and Age Associated Memory Impairment.
JAMA. 2017;317(7):717 to 727. PMID 28241356

14 **Snyder PJ, et al.** Testosterone Treatment and Fractures in Men with Hypogonadism.
N Engl J Med. 2024;390(3):203 to 211. PMID 38231621

15 **Budoff MJ, et al.** Testosterone Treatment and Coronary Artery Plaque Volume in Older Men With Low Testosterone.
JAMA. 2017;317(7):708 to 716. PMID 28241355

16 **Bhasin S, et al.** Prostate Safety Events During Testosterone Replacement Therapy in Men With Hypogonadism: A Randomized Clinical Trial.
JAMA Netw Open. 2023;6(12):e2348692. PMID 38150256

17 **Nackeeran S, et al.** The Effect of Route of Testosterone on Changes in Hematocrit: A Systematic Review and Bayesian Network Meta Analysis of Randomized Trials.
J Urol. 2022;207(1):44 to 51. PMID 34445892

18 **Pfizer (Pharmacia & Upjohn).** DEPO Testosterone (testosterone cypionate) label, revised September 2025.
DailyMed: dailymed.nlm.nih.gov, accessed 4 November 2026.

19 **American Urological Association.** Testosterone Deficiency Guideline, unabridged version.
Published 2018; validity confirmed 2024. auanet.org, accessed 4 November 2026.

20 **Hikma Pharmaceuticals USA.** Testosterone enanthate injection label, revised June 2025.
DailyMed: dailymed.nlm.nih.gov, accessed 4 November 2026.

21 **Endo USA.** TESTOPEL (testosterone pellets) label, revised July 2025.
DailyMed: dailymed.nlm.nih.gov, accessed 4 November 2026.

22 **U.S. Food and Drug Administration.** FDA issues class wide labeling changes for testosterone products.
Drug alerts and statements, 28 February 2025. fda.gov

23 **AbbVie (Ascend Therapeutics).** ANDROGEL 1.62% label, revised July 2025, sections 5 and 6.1.
DailyMed: dailymed.nlm.nih.gov, accessed 4 November 2026.

24 **U.S. Food and Drug Administration.** Testosterone Information.
Postmarket drug safety information, content current as of 23 June 2026. fda.gov

25 **U.S. Department of Health and Human Services.** FDA requests updates to testosterone therapy labeling.
Press release, 18 June 2026. hhs.gov

26 **U.S. Food and Drug Administration.** Compounding and the FDA: Questions and Answers.
Content current as of 16 September 2025. fda.gov

27 **World Anti Doping Agency.** The 2026 Prohibited List, S1 Anabolic agents.
In force from 1 January 2026. WADA, accessed 4 November 2026.

28 **U.S. Anti Doping Agency.** TUE Application for Testosterone: Physician Worksheet.
Dated 17 December 2020. usada.org, accessed 4 November 2026.

29 **U.S. Food and Drug Administration.** Compounding laws and policies.
Describes the conditions of sections 503A and 503B, including patient specific prescriptions, current good manufacturing practice requirements for outsourcing facilities, adverse event and product reporting, and risk based inspection. Content current as of 17 December 2024. fda.gov, accessed 4 November 2026.

30 **U.S. Food and Drug Administration.** Warning letter to Royal Peptides LLC.
Center for Drug Evaluation and Research, 24 August 2026. States that products marketed for research use only are intended to be drugs for human use and are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act. fda.gov, accessed 4 November 2026.

OC WELLNESS
NEWPORT BEACH

IMPORTANT NOTICE

This document is patient education prepared by OC Wellness. It is not medical advice, not a prescription, and not a promise of any clinical outcome. **Testosterone cypionate and testosterone enanthate injections and Testopel pellets are approved by the U.S. Food and Drug Administration for men with low testosterone caused by specific disorders of the testes, pituitary or hypothalamus; testosterone is a Schedule III controlled substance, and compounded testosterone is not FDA approved.** Individual results vary, and no outcome can be predicted from the studies cited here.

Clinical services at OC Wellness are provided by licensed physicians and clinicians through the supervising professional medical corporation. Family MSO Holdings LLC provides management and administrative services only. It does not practice medicine, employ physicians in the practice of medicine, or influence clinical judgment. All treatment decisions are made solely by your licensed treating physician.

Do not begin, stop, or change any medication or supplement based on this document. Discuss it with your physician, and disclose every prescription drug, over the counter product, and supplement you take.

PATIENT SIGNATURE **DATE** **REVIEWING PHYSICIAN**

OCW WP 055 · Version 1.0 · 4 November 2026 · Next scheduled literature review: May 2027 · Prepared with sources indexed in PubMed and federal public records. OC Wellness · Newport Beach, California · ocwellness.com · (949) 222 0232