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IN BRIEF

Label Changes for Testosterone Products

The FDA has required changes in the labels of all testosterone products to reflect new data on their cardiovascular effects. The updated labels will no longer include a boxed warning about an increased risk of adverse cardiovascular outcomes, but will contain a new warning about an increase in blood pressure.¹

TESTOSTERONE REPLACEMENT THERAPY – All testosterone replacement products available in the US are FDA-approved for treatment of males with conditions associated with a deficiency or absence of endogenous testosterone. No testosterone products are approved for treatment of low testosterone levels due solely to aging.

CLINICAL STUDIES – The label changes were based on the results of a double-blind trial (TRAVERSE) and post-marketing ambulatory blood pressure monitoring studies.

Cardiovascular Outcomes – In the TRAVERSE trial, 5246 hypogonadal men 45-80 years old who had or were at high risk for cardiovascular disease were randomized to receive transdermal testosterone gel (AndroGel 1.62%) or placebo once daily. After a mean follow-up of 33 months, the incidence of a first occurrence

of nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death with testosterone was noninferior to that with placebo (7.0% vs 7.3%). The change in mean systolic blood pressure from baseline through 6 months was +0.3 mm Hg with testosterone and -1.5 mm Hg with placebo.²

Blood Pressure – Based on premarketing studies showing increases in blood pressure with use of oral or subcutaneous testosterone, the FDA required post-marketing studies for all testosterone products. The trials found that testosterone use, regardless of the route of administration, was associated with increases in blood pressure.³⁻⁵ ■

1. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. February 28, 2025. Available at: <https://bit.ly/43FMIFI>. Accessed March 27, 2025.
2. AM Lincoff et al. Cardiovascular safety of testosterone-replacement therapy. *N Engl J Med* 2023; 389:107.
3. MD Efos et al. Ambulatory blood pressure parameters among men with hypogonadism treated with testosterone transdermal therapy. *Endocr Pract* 2024; 30:847.
4. WB White et al. Effects of oral testosterone undecanoate Kyzatrex on ambulatory blood pressure in hypogonadal men. *J Clin Hypertens (Greenwich)* 2021; 23:1420.
5. MA Weber et al. Single-arm study of testosterone gel replacement therapy and ambulatory blood pressure outcomes in men with hypogonadism. *Andrology* 2024 October 9 (epub).

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