



**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**

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FDA 要求製造廠商更正 testosterone 成分藥品說明書上使用目的，並註記使用 testosterone 成分藥品可能增加發生中風、心臟病發之風險。FDA 提出警示，testosterone 製劑只核准處方於睪丸、腦下垂體或腦部疾病導致體內 testosterone 濃度不足的男性病人，目前 testosterone 製劑用於治療老化引起的睪固酮濃度過低，治療效益與安全性均尚未明確。

**建議**

FDA 建議，testosterone 製劑只能處方於特定疾病導致體內 testosterone 濃度過低的男性病人，且須經過數值檢驗確認後才可處方 testosterone。醫療人員應告知病人服用 testosterone 製劑可能增加心臟疾病的風險，病人於服藥期間若出現胸痛、呼吸短促、身體單側無力、口齒不清等類似心臟病或中風的現象，應儘速就醫。

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**AUDIENCE:** Health Professional, Endocrinology, Urology, Family Practice, Patient

**ISSUE:**

FDA is requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. FDA is also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. FDA cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone.

**BACKGROUND:**

Testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause hypogonadism. However, FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established.

**RECOMMENDATION:**

Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests. Health care professionals should make patients aware of the possible increased cardiovascular risk when deciding whether to start or continue a patient on testosterone therapy. Patients using testosterone should seek medical attention immediately if symptoms of a heart attack or stroke are present, such as chest pain, shortness of breath or trouble breathing, weakness in one part or one side of the body, or slurred speech.