

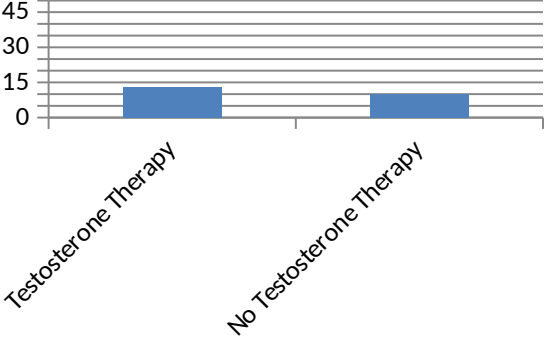
Testosterone Products Evaluation: FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products

Safety Announcement

Drug	FDA-Approved Testosterone Products
Drug Safety Risk	<ul style="list-style-type: none"> • Two recent studies show a possible increased risk of stroke, heart attack, or death with FDA-approved testosterone products • These studies are not conclusive • FDA is investigating this risk
Patient Action	<ul style="list-style-type: none"> • Talk with your health care professional if you have any questions or concerns • Do not stop taking prescribed testosterone products without consulting your health care professional first
Healthcare Professional Action	<ul style="list-style-type: none"> • Consider whether the benefits of treatment are likely to exceed the potential risks. • Follow the prescribing information in the drug labels
Basis for Concern	<ul style="list-style-type: none"> • Two separate studies recently published suggested an increased risk of cardiovascular events, including stroke, heart attack and death, among groups of men prescribed testosterone therapy. • FDA has not verified the study data • FDA has not concluded that FDA-approved testosterone products increase the risk of stroke, heart attack, or death. • One study found that about 13 out of every 100 prescribed testosterone therapy suffered a stroke, heart attack, or death. <ul style="list-style-type: none"> ○ In comparison, only 10 of every 100 men who were not taking the drug suffered a stroke, heart attack, or death in the same study. ○ This study suggests that participants in this study taking testosterone had a 30 percent higher risk of experiencing these side effects than those who were not taking it.

100
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Number of participants out of every 100 followed who experienced a cardiovascular event or death

	 <ul style="list-style-type: none"> • The second study found the risk of a heart attack doubled among men older than 65 years in the first 90 days after they started testosterone therapy. <ul style="list-style-type: none"> ○ For men younger than 65 who already had heart disease, the second study reported the risk of heart attack in the first 90 days was two to three times greater than among those who did not take the drug. ○ The study found no increased risk of heart attack in younger men taking testosterone therapy who did not have heart disease.
FDA Response	<ul style="list-style-type: none"> • FDA has not concluded that FDA-approved testosterone products increase the risk of stroke, heart attack, or death • We are providing this alert while we continue to evaluate the information from these studies and other available data • We will communicate our final conclusions and recommendations when our evaluation is complete
About Testosterone	<p>Testosterone is a hormone essential to the development of male growth and masculine characteristics.</p>
About Testosterone Products	<ul style="list-style-type: none"> • FDA-approved testosterone formulations include the topical gel; transdermal patch; buccal system, which is applied to upper gum or inner cheek, and injection. • Testosterone products are FDA-approved <u>only</u> for use in men who lack or have low testosterone levels in conjunction with an associated medical condition, for example, genetic problems or chemotherapy that cause the testicles to stop producing necessary testosterone.
Data Summary Information on This Risk	<p>The first publication that prompted FDA to reassess the cardiovascular safety of testosterone therapy was an observational study of older men in the U.S. Veteran Affairs health system published in the <i>Journal of the American Medical Association (JAMA)</i> in November 2013. The men included in this study had low serum testosterone. They were undergoing imaging of the blood vessels of the heart, called coronary angiography, to assess for coronary artery disease. Some of the men received testosterone treatment while others did not. On average, the men who entered the study were about 60 years old, and many had underlying cardiovascular disease. This study suggested a 30 percent increased risk of stroke, heart attack, or death among men prescribed testosterone</p>

	<p>therapy.</p> <p>A second observational study reported an increased risk of heart attack in older men, as well as in younger men with pre-existing heart disease, who filled a prescription for testosterone therapy. The study reported that the risk of a heart attack doubled among men 65 years and older in the first 90 days following the first prescription. Among men younger than 65 years old with a pre-existing history of heart disease, the study reported a two to three times greater risk of heart attack in the first 90 days following a first prescription. However, younger men without a history of heart disease who filled a prescription for testosterone did not have an increased risk of heart attack.</p>
Additional Information	Patients and health care professionals should report side effects to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page
What is FDA?	FDA includes pharmacists, doctors, nurses, researchers and other health professionals. We also work with external experts. We protect public health by assuring drugs are safe and effective.