

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

The [testosterone product labels \(https://web.archive.org/web/20170722185733/http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name\)](https://web.archive.org/web/20170722185733/http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name) have been updated. The revised labels clarify the approved uses of these medications and include information about a possible increased risk of heart attacks and strokes in patients taking testosterone.

This information is an update to the FDA Drug Safety Communication: FDA Evaluating Risk of Stroke, Heart Attack, and Death with FDA-Approved Testosterone Products issued on [January 31, 2014 \(/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/ucm383904.htm\)](https://www.fda.gov/Drugs/DrugSafety/ucm383904.htm).

Safety Announcement

[03-03-2015] The U.S. Food and Drug Administration (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. We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.

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 a condition called hypogonadism. Examples of these disorders include failure of the testicles to produce testosterone because of genetic problems, or damage from chemotherapy or infection. 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.

In addition, based on the available evidence from published studies and expert input from an [Advisory Committee meeting \(ssLINK/UCM404895\)](https://www.fda.gov/oc/ohrt/20170722185733/ucm404895), FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use. These studies included aging men treated with testosterone. Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not.

Based on our findings, we are requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use. Health care professionals should make patients aware of this possible risk when deciding whether to start or continue a patient on testosterone therapy. We are also requiring manufacturers of approved testosterone products to conduct a well-designed clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of these products. We are encouraging these manufacturers to work together on a clinical trial, but they are allowed to work separately if they so choose.

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
- Slurred speech

A list of FDA-approved testosterone products can be found by searching for “testosterone” at [Drugs@FDA \(https://web.archive.org/web/20170722185733/http://www.accessdata.fda.gov/scripts/cder/drugsatfda/\)](https://www.accessdata.fda.gov/scripts/cder/drugsatfda/).

We urge health care professionals and patients to report side effects involving testosterone products to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

[**Facts about testosterone**](#) ▼

[**More Info for Patients**](#) ▼

[**More Info for Health Care Professionals**](#) ▼

[Data Summary](#) ▼[References](#) ▼

[en Español \(/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/ucm438294.htm\)](https://www.fda.gov/Drugs/DrugSafety/ucm438294.htm)

[Drug Safety Communication \(/web/20170722185733/https://www.fda.gov/downloads/Drugs/DrugSafety/UCM436270.pdf\)](https://www.fda.gov/downloads/Drugs/DrugSafety/UCM436270.pdf) (PDF - 74KB)

Related Information

- [Testosterone Information \(/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm161874.htm\)](https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm161874.htm)

Contact FDA

For More Info

855-543-DRUG (3784)
and press 4
druginfo@fda.hhs.gov
(<https://web.archive.org/web/20170722185733/mailto:druginfo@fda.hhs.gov>)

Report a Serious Problem to MedWatch

Complete and submit the report [Online](https://www.accessdata.fda.gov/scripts/medwatch/) (<https://web.archive.org/web/20170722185733/https://www.accessdata.fda.gov/scripts/medwatch/>).
[Download form \(https://web.archive.org/web/20170722185733/http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf\)](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

<u>More in Drug Safety and Availability (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/default.htm)</u>	
<u>Drug Alerts and Statements (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/ucm215175.htm)</u>	
<u>Medication Guides (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm)</u>	
<u>Drug Safety Communications (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm)</u>	
<u>Drug Shortages (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm)</u>	▼
<u>Postmarket Drug Safety Information for Patients and Providers (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)</u>	▼
<u>Information by Drug Class (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/default.htm)</u>	
<u>Medication Errors (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm)</u>	
<u>Drug Safety Podcasts (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm)</u>	▼
<u>Safe Use Initiative (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm)</u>	▼
<u>Drug Recalls (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/DrugRecalls/default.htm)</u>	
<u>Drug Supply Chain Integrity (/web/20170722185733/https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm)</u>	▼