

Testosterone Products – New Warning

- On October 25, 2016, the [FDA announced](#) the approval of class-wide labeling changes for all prescription testosterone products, including a new warning and updating the *Abuse and Dependence* section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS).
- Prescription testosterone products are schedule III controlled substances and are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. Examples of these conditions include failure of the testicles to produce testosterone because of genetic problems, or damage to the testicles from chemotherapy or infection.
 - FDA-approved testosterone formulations include topical gel (eg, [AndroGel](#)[®], [Fortesta](#)[®], [Testim](#)[®], [Vogelxo](#)[™]), topical solution ([Axiron](#)[®]), transdermal patch (eg, [Androderm](#)[®]), buccal system ([Striant](#)[®]), injection (eg, [testosterone cypionate](#)), nasal gel ([Natesto](#)[™]), and an implantable pellet ([Testopel](#)[®]).
- According to the [National Institute on Drug Abuse](#), testosterone, [nandrolone](#), [oxandrolone](#), oxymethalone, and stanozolol are some of the most frequently abused AAS.
- The new warning will alert prescribers to the abuse potential of testosterone and related serious adverse outcomes, especially those that affect the heart and mental health. The *Abuse and Dependence* section will be updated with similar information.
- The *Warning and Precautions* section will also advise prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.
- Testosterone and other AAS are abused by adults and adolescents, including athletes and body builders. Abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system.
 - Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility.
 - Individuals abusing high doses of testosterone have also reported withdrawal symptoms such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia.