

## FDA: Kids at risk from testosterone gel

May 7 2009, By RICARDO ALONSO-ZALDIVAR , Associated Press  
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(AP) -- A little testosterone might be good for adults, but it can cause serious harm to children, federal health officials warned Thursday. The Food and Drug Administration said adults using prescription testosterone gel must be extra careful not to get any of it on children to avoid causing serious side effects.

These include enlargement of the genital organs, [aggressive behavior](#), early aging of the bones, premature growth of pubic hair, and increased sexual drive.

Boys and girls are both at risk.

The agency ordered its strongest warning on the products - a so-called black box.

The problems arise if [adults](#) don't wash their hands well.

Also, since [testosterone](#) gel is usually applied to the upper arms or shoulders, adults must cover up to keep kids from accidentally touching a spot that has the medicine on it.

Testosterone gel is used by men whose bodies no longer make the sex hormone, or who have very low levels of it. Doctors sometimes prescribe it to women to increase sexual drive, although the FDA has not approved that use.

U.S. pharmacies dispensed about 1.8 million prescriptions in 2007 for testosterone gel, with the leading brand, AndroGel, accounting for about three-fourths of the sales.

"These drugs are approved for an important medical need, but can have serious unintended side effects if not used properly," Dr. Janet Woodcock, director of the FDA's drug division, said in a statement. "We must ensure that the adults using them are well-informed about the precautions needed to protect children."

Although current drug warnings recommend that people using the gels wash and cover up, some patients are apparently not heeding the advice.

The FDA said it received reports of eight cases since the beginning of December in which children were accidentally exposed to testosterone gels. The kids ranged in age from nine months to five years. Only a small fraction of cases in which there is a problem with a drug are reported to the FDA, so there could be many more.

Health officials said in most cases the signs and symptoms went away once testosterone gel was identified as the cause of the problem and adults took the proper precautions.

But in some children, enlarged sex organs did not return to their appropriate size, and bone age remained somewhat higher than the child's chronological age. One child underwent surgery because the link to testosterone gel was not recognized right away.

Health officials are recommending that adults who use testosterone gel wash their hands with warm soap and water after each use and cover their skin after the gel has dried. Pregnant women, and those who may become pregnant, should avoid any exposure, since it could lead to birth defects.

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On the Net:

FDA press release: <http://tinyurl.com/dnkyeo>

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