# Therapeutic Use of Androgens in Women

Hormone Health NETWORK®

## A PATIENT'S GUIDE

Androgens, like testosterone, are generally thought of as male hormones but are also present in women in small amounts. While androgen deficiency (AD) can be diagnosed with little trouble in men, the same is not true for women.

Media stories about how testosterone increases libido (sexual desire) in women with AD have fueled interest in obtaining androgen therapy. In the popular media, testosterone has been promoted as "the hormone of desire." The dilemma that doctors face is that there is a lack of long-term studies to back up its use in women.

This patient guide is based on clinical guidelines written by an expert group of doctors from The Endocrine Society. The guide summarizes what is currently known about the value of short-term testosterone use in selected groups of women, while emphasizing what is not known about the long-term effects and safety of androgen therapy in women. With this lack of clear data, the expert panel that developed the clinical guidelines has recommended specific areas of research to address these issues.

These guidelines do not apply to women who want to take testosterone to improve their strength, athletic performance, or physical appearance, or to prevent aging. Using testosterone for these purposes may be harmful to your health.

### Why do the clinical guidelines recommend against making a diagnosis of AD in women at present?

At present, there is no well-defined clinical AD syndrome in women, nor is there definitive information on testosterone levels in women as they get older. Testosterone levels do appear to decrease somewhat between ages 20 and 40 in women, but there does not appear to be an abrupt and profound reduction, similar to that of estrogens, at the time of menopause. Some groups of women, for example those who have had both ovaries removed, whose adrenal or pituitary glands do not function properly, or who use certain medications, do have lower androgen levels than healthy women.

In addition, despite claims in the popular media that getting testosterone levels checked is "a small blood test, not a big deal," the situation is actually more complex than that. Testosterone exists in two forms—bound to a protein in blood and "free" of that binding. It is believed that the free testosterone is biologically active (i.e., the only portion of testosterone that is able to act in the body). Blood tests that measure androgens have not been optimized to measure the low free testosterone levels found in women. Thus, if "standard" values are lacking for women of different ages, it is difficult to use a blood test to define AD.

### What is known about testosterone therapy and women's sexual function?

To date, the main evidence that testosterone has a role in women's sexual function comes from women who have had their ovaries removed (surgical menopause) before natural menopause and are complaining of sexual dysfunction (lack of desire). Transdermal (skin patch) testosterone preparations have shown improvement in sexual function in this group who also took estrogen. However, the issue that stands in the way of its broad recommendation is that women beginning therapy may wish to remain sexually active indefinitely, and this raises concerns about the long-term safety of testosterone therapy when combined with estrogen therapy (HT). There are currently no data for sexual benefit of transdermal testosterone in women with low estrogen levels.

## How is testosterone therapy administered to women?

Testosterone products tested in clinical trials involving women come in oral (pill), transdermal, injectable, and implant forms. Methyltestosterone, the most commonly used oral preparation, is usually given combined with estrogen. The product is FDA approved only for use to treat vasomotor symptoms (e.g., hot flashes) associated with menopause, but it has been used off-label to treat decreased libido in postmenopausal women. Recently, the FDA did not approve a transdermal patch product for treatment of female sexual dysfunction without further safety and effectiveness studies. Potential specific risks of some of these preparations include hirsutism (unwanted hair growth), acne, male pattern balding, and deepening of the voice. And oral androgens lower HDL, known as "good" cholesterol.

Testosterone products made for men are not safe for women because they deliver doses that are too high and cannot be reliably parceled for appropriate dosing for women.

## Why do the clinical guidelines recommend against the generalized use of testosterone by women?

In the United States, testosterone therapy is not approved for use in women for AD. Some compounding pharmacies, which make products according to a doctor's specifications, and over-the-counter products sold in health food stores have bypassed this restriction by providing personalized testosterone therapy. Problems with this approach include the lack of quality assurance for these substances. Examples include the widely available body-building supplements dehydroepiandrosterone (DHEA) and androstenedione, which are precursor hormones (or prohormones). These have minimal activity on their own but once in the body, they can be converted to active androgens like testosterone, as well as to estrogens, and cause dangerous side effects.

There are no data on the safety and efficacy of physiologic testosterone therapy (i.e., administration of enough testosterone to bring a patient's level up to normal) for longer than 24 weeks. The data on use of DHEA and androstenedione are even weaker. Because of these deficiencies, the panel recommended against the routine use of testosterone therapy in women until further research is completed.

The task force recommended that, in addition to defining AD and determining the effectiveness of testosterone therapy in treating associated syndromes, future studies should examine the following safety issues:

- Alterations in the endometrium (lining of the womb that can be at risk for cancer) after testosterone therapy, with and without estrogen therapy
- Effects of testosterone therapy on the breast, with and without estrogen therapy
- Effects on risk factors for heart disease
- Risk for side effects such as hirsutism, acne, balding, and voice deepening

## What can you do to help your treatment process?

You and your doctor should be partners in your care. It is important that you provide a full description of your symptoms to your doctor. Many different physiological and psychological factors are involved in women's sexual function and dysfunction, not just certain hormones, and those factors should be evaluated before you begin a treatment plan.

Because of their potentially dangerous side effects, you should never take testosterone supplements on your own without consulting with your doctor. Follow your doctor's recommendations, keep regular appointments, and ask questions.

**EDITORS**

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Note to health care professionals: This patient guide is based on, and is intended to be used in conjunction with, the Endocrine Society's clinical practice guidelines (available at www.endocrine.org/guidelines/index.cfm).