INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION[1,2]

AndroGel® (testosterone gel) 1% and 1.62% CIII are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.

Limitations of use:

- Safety and efficacy of AndroGel 1% and 1.62% in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
- Safety and efficacy of AndroGel in males less than 18 years old have not been established.
- Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure

IMPORTANT SAFETY INFORMATION[1,2]

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- **Virilization has been reported in children who were secondarily exposed to testosterone gel.**
- **Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.**
- **Healthcare providers should advise patients to strictly adhere to recommended instructions for use.**

- AndroGel is contraindicated in men with breast cancer or known or suspected prostate cancer, and in women who are pregnant, as testosterone can cause virilization of the female fetus and is teratogenic and may cause fetal harm.

- Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH.
- Patients treated with androgens may be at increased risk for prostate cancer and should be evaluated prior to initiating and during treatment with androgens. Monitor prostate specific antigen (PSA) levels periodically.
- Avoid unintentional exposure of women or children to AndroGel. Secondary exposure to testosterone can produce signs of virilization. AndroGel should be promptly discontinued until the cause of virilization is identified. Exposure of a pregnant woman to AndroGel may result in potential hazard to the fetus.
- Increases in hematocrit, reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone. An increase in red blood cell mass may increase the risk of thromboembolic events. Monitor hematocrit prior to and periodically during treatment. Monitor hemoglobin periodically.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone products such as AndroGel. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue AndroGel and initiate appropriate workup and management.
- Some studies, but not all, have reported an increased risk of major cardiovascular events (MACE) in association with use of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use AndroGel.
- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If abuse is suspected, check serum testosterone concentrations and counsel patients concerning the serious adverse reactions associated with abuse. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
- AndroGel is not indicated for use in women.
- Treatment with AndroGel may lead to azoospermia; edema, which may be serious in patients with preexisting cardiac, renal, or hepatic disease or in patients taking adrenocorticotropic hormone (ACTH) or corticosteroids; gynecomastia; sleep apnea, especially in those with risk factors; changes in insulin sensitivity or glycemic control; and changes in anticoagulant activity.

- Treatment with androgens may lead to serious hepatic effects. AndroGel is not known to cause these adverse effects. Monitor liver function tests (LFTs) periodically.
- Changes in serum lipid profile may require dose adjustment or discontinuation of testosterone therapy. Monitor lipid concentrations periodically.
- Androgens should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Regular monitoring of serum calcium concentrations is recommended in these patients.
- Most common adverse reaction of AndroGel 1.62% (incidence ≥5%) is an increase in prostate specific antigen (PSA). Most common adverse reactions of AndroGel 1% (incidence ≥5%) are acne, application site reactions, abnormal lab tests, and prostatic disorders.
- **Dosage and administration for AndroGel 1.62% differs from AndroGel 1%. AndroGel is not interchangeable with other topical testosterone products.**

Use in specific populations:

There are insufficient long-term safety data in geriatric patients using AndroGel to assess the potentially increased risks of cardiovascular disease and prostate cancer.

References: 1. AndroGel 1.62% [package insert]. ASCEND Therapeutics US, LLC, Morristown, NJ. 2022 **2.** AndroGel 1% [package insert]. ASCEND Therapeutics US, LLC, Morristown, NJ, 2022.

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