

**Name in Cyrillic:** Андрогель®

**Active substance:** Testosterone

**Pharmacologic effect:** androgenic

**Pharmacodynamics:**

Endogenous androgens, mainly testosterone, secreted by the testicles, and their main metabolite, dihydrotestosterone, are responsible for the development of the external and internal genital organs, the development and maintenance of secondary sexual characteristics (stimulation of hair growth, coarsening of the voice, development of libido). They affect protein anabolism; development of skeletal muscles and distribution of subcutaneous fat; help reduce urinary excretion of nitrogen, sodium, potassium, chlorides, phosphates and water. Testosterone does not cause testicular development: it reduces pituitary secretion of gonadotropins.

The effects of testosterone on some target organs appear after the peripheral conversion of testosterone to estradiol, which then binds to estrogen receptors in the nuclei of target organ cells (such as the pituitary, adipose tissue, brain, bones).

**Pharmacokinetics:**

The degree of absorption of testosterone through the skin varies within 9-14% of the applied dose.

After absorption through the skin, testosterone enters the systemic circulation in relatively constant concentrations for 24 hours.

Serum testosterone concentration increases from the 1st hour after the use of AndroGel®, reaching a constant value from the 2nd day of treatment. Daily fluctuations in testosterone concentrations have the same amplitude as the changes in the content of endogenous testosterone observed in circadian rhythms. With the external route of administration of the drug, there are no supraphysiological peaks in the concentration of testosterone in the blood that occur during the injection method of application.

In contrast to oral androgen therapy, the external use of the drug does not cause an increase in steroid concentrations in the liver above physiological norms. The use of AndroGel® at a dose of 5 g causes an average increase in plasma testosterone concentration of approximately 2.5 ng / ml (8.7 nmol / l).

After discontinuation of treatment, the concentration of testosterone begins to decline approximately 24 hours after the last dose. The concentration returns to baseline approximately 72-96 hours after the last dose.

The main active metabolites of testosterone are dihydrotestosterone and estradiol.

The drug AndroGel® is excreted mainly by the kidneys and through the intestines in the form of conjugated testosterone metabolites.

**Indications:**

Replacement therapy for hypogonadism in men when testosterone deficiency is confirmed by clinical symptoms and laboratory tests.

**Contraindications:**

hypersensitivity to testosterone and / or any excipient in the composition of the drug;

diagnosed prostate cancer (or suspicion of it);

diagnosed breast cancer (or suspicion of it);

age up to 18 years (due to the lack of data on the efficacy and safety of testosterone use in this age population).

AndroGel® is not indicated for use in women.

**Use with caution:**

in patients with malignant neoplasms (due to the risk of hypercalcemia and hypercalciuria); severe heart, kidney or liver failure; ischemic heart disease; diabetes mellitus, benign prostatic hyperplasia, arterial hypertension, epilepsy, migraine, a history of sleep apnea, over the age of 65; in the presence of thrombophilic conditions or risk factors for venous thromboembolism (VTE); in patients receiving oral anticoagulants.

### **Pregnancy and breast-feeding:**

AndroGel® is not indicated for use in women. Pregnant women should avoid any contact with the drug and gel application sites due to the possible adverse virilizing effect of testosterone on the female fetus. In case of contact with the skin, wash the contact area with soap and water as soon as possible.

### **Side effects:**

The most common adverse reactions in the application of testosterone at the recommended daily dose (5 g of gel per day) were skin reactions at the site of application, erythema, acne, dry skin.

### **Interaction:**

**Oral anticoagulants :** Changes in anticoagulant activity (it is possible to enhance the effect of an oral anticoagulant by modifying the synthesis of hepatic coagulation factors and competitive inhibition of binding to plasma proteins). Patients should be closely monitored for prothrombin time and INR, especially at the start and/or end of testosterone therapy.

**Glucocorticosteroids (GKS):** Simultaneous use of testosterone with adrenocorticotrophic hormone (ACTH) or corticosteroids may increase the risk of edema.

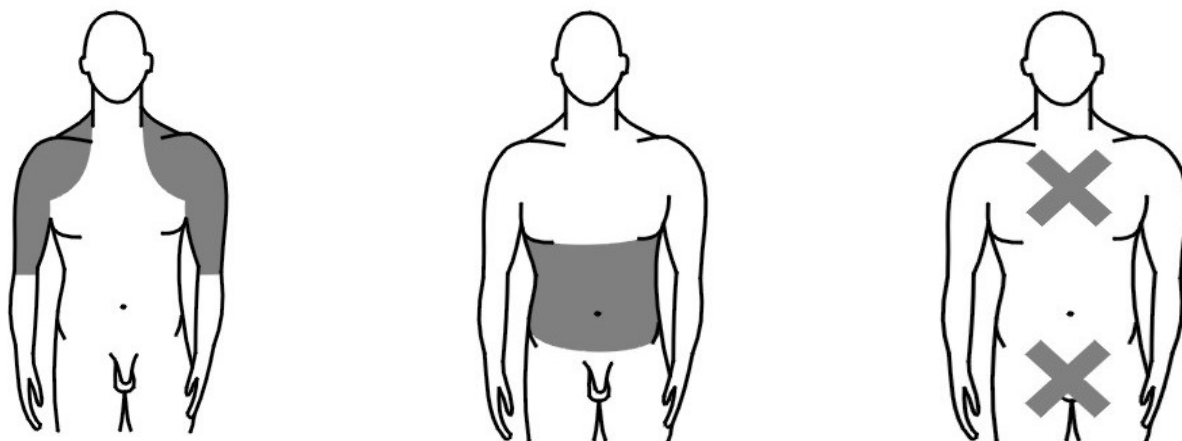
**Impact on laboratory data:** Androgens can reduce the concentration of thyroxin-binding globulin, leading to a decrease in serum T4 concentrations and an increase in sensitivity to T3 and T4. The concentrations of free thyroid hormones, however, remain unchanged, and there are no clinical manifestations of hypothyroidism.

**Effect on glycemic control:** During androgen therapy, changes in insulin sensitivity and glucose tolerance, glucose concentration and glycated hemoglobin in the blood were registered.

### **Dosing and Administration:**

The recommended dose is 5 g of gel (i.e. 50 mg of testosterone) applied once a day at about the same time, preferably in the morning. The individual daily dose may be adjusted by the physician depending on clinical and laboratory parameters in patients, but should not exceed 10 g of gel per day. Correction of the dose of testosterone should be carried out in stages of 2.5 g of gel per day. A constant concentration of testosterone in the blood plasma is reached approximately on the 2nd day of using AndroGel®. To adjust the dose of AndroGel®, it is necessary to determine the concentration of testosterone in the blood plasma in the morning, before applying the gel to the skin, from the 3rd day after the start of treatment (within one week). The dose of the drug can be reduced with an increase in the concentration of testosterone in the blood plasma. With a decrease in the concentration of testosterone in the blood plasma, the dose of AndroGel® can be increased, but not more than 10 g of gel per day.

The application of the gel is carried out by the patient himself **on clean, dry, intact skin** of the shoulder, forearm or abdomen. Do not apply the gel to the vulva area, because the high content of ethyl alcohol in the preparation may cause local irritation.



After removing the gel from the bag in the palm of your hand, you should immediately apply it to the skin. The gel is applied gently in a thin layer. No need to rub the gel into the skin. Let the gel dry for 3-5 minutes. After applying the gel to the skin, wash your hands with soap and water.

**Overdose:**

Symptoms: Plasma testosterone concentration should be determined in the presence of clinical signs and symptoms suggesting excessive exposure to androgens. In case of an overdose of AndroGel®, cases of rashes at the site of application of the gel have been reported.

Treatment: you should immediately wash the site of application of the gel and stop therapy on the recommendation of the attending physician.

**Special instructions:**

Athletes should be informed that the drug contains testosterone as an active substance, which can give a positive result in doping control.

Potential transfer of testosterone:

In the absence of precautionary measures, the transfer of testosterone to another person after the use of the drug can occur at the time of close skin contact with the gel application area, which leads to an increase in testosterone concentration and in case of repeated contact (accidental androgenization) to the possible occurrence of adverse reactions (increased facial hair growth and / or body, lowering the timbre of the voice, menstrual irregularities in women). When prescribing AndroGel®, the doctor should inform the patient about the risk of testosterone transfer, for example, through contact between persons, including children, as well as about safety measures. To ensure the safety of the partner, the patient should, for example, be advised to have sexual intercourse before using the drug or to observe the interval between the use of AndroGel® and sexual intercourse. If sexual intercourse is carried out within 6 hours after application of AndroGel®, during the period of contact it is recommended to wear a T-shirt covering the site of application of the gel or take a shower before intercourse.

It is preferable to observe an interval of at least 6 hours between applying the gel and taking a bath or shower.

However, occasional showering between 1 and 6 hours after gel application does not significantly affect treatment.

The following precautions are recommended:

For the patient:

- wash your hands with soap after applying the gel;
- cover the gel application area with clothing after the gel has dried;
- take a shower before contact with a partner.

For persons not using AndroGel®:

- in case of contact with the area of application of the gel, not previously washed with water, it is necessary to immediately wash the skin area with soap and water where testosterone could get;
- it is necessary to inform the doctor about the appearance and development of signs of hyperandrogenization, such as acne or a change in normal hair growth.

If the partner is pregnant, the patient needs to be more careful about the precautions. Pregnant women should avoid any contact of the drug with the skin. In case of contact with the drug, a woman should wash the contact area with soap and water as soon as possible.

When in contact with children, it is recommended to wear a T-shirt covering the site of application of the gel to avoid the risk of children's skin contact with the drug.

AndroGel® should not be administered to patients who cannot comply with safety instructions (for example, severe chronic alcoholism, substance abuse, severe mental disorders).

**Manufacturer:** Besins Healthcare (Belgium)

**Reliable supplier with fast Worldwide shipping:**

RussianMeds Online Store

<https://russianmeds.com>

**Storage:**

The temperature is not above 25 °C (77 °F). Keep out of the reach of children.