

# ANDROGEL® (TESTOSTERONE GEL)

## Registration number:

LS-000869-151012 [ЛС-000869-151012]

## Trade name:

AndroGel®

## International non-proprietary name (INN):

Testosterone

## Dosage form:

Gel for external use

## Composition:

Per 1 g of gel:

**Active ingredient:** Testosterone – 10 mg

**Excipients:** Isopropyl myristate – 5 mg, Carbomer 980 – 9 mg, Sodium hydroxide – 47.2 mg, Ethanol 96% – 0.714 g, Purified water – up to 1 g

Per 2.5 g sachet:

**Active ingredient:** Testosterone – 25 mg

**Excipients:** Isopropyl myristate – 12.5 mg, Carbomer 980 – 22.5 mg, Sodium hydroxide – 118 mg, Ethanol 96% – 1.785 g, Purified water – up to 2.5 g

Per 5 g sachet:

**Active ingredient:** Testosterone – 50 mg

**Excipients:** Isopropyl myristate – 25 mg, Carbomer 980 – 45 mg, Sodium hydroxide – 236 mg, Ethanol 96% – 3.570 g, Purified water – up to 5 g

Per 1.25 g dose from pump bottle:

**Active ingredient:** Testosterone – 12.5 mg

**Excipients:** Isopropyl myristate – 6.25 mg, Carbomer 980 – 11.25 mg, Sodium hydroxide – 59 mg, Ethanol 96% – 0.892 g, Purified water – up to 1.25 g

## Description:

Transparent or slightly opalescent, colorless gel with an alcohol-like odor.

## Pharmacological group:

Androgen

## ATC code:

G03BA03

## Pharmacological properties:

### Pharmacodynamics:

Endogenous androgens, mainly testosterone secreted by the testes, and their primary metabolite, dihydrotestosterone, are responsible for the development of external and internal genitalia, secondary sexual characteristics, libido, protein anabolism, skeletal muscle development, fat distribution, and reduced urinary excretion of nitrogen, sodium, potassium, chloride, phosphates, and water. Testosterone does not promote testicular development but reduces pituitary secretion of gonadotropins.

Some effects of testosterone on target organs occur after peripheral conversion to estradiol, which binds to estrogen receptors in tissues such as the pituitary, adipose tissue, brain, and bones.

### Pharmacokinetics:

The absorption of testosterone through the skin is approximately 9–14% of the applied dose.

After absorption, testosterone enters the systemic circulation at relatively stable concentrations over 24 hours.

## Indications:

Replacement therapy for testosterone deficiency in men

## Contraindications:

Androgens are contraindicated in the following cases:

- Presence or suspected presence of breast carcinoma or prostate cancer.
- Known hypersensitivity to testosterone or other components of the drug.

There is no experience with the use of Androgel in women or children.

### **Use with caution:**

- Malignant tumors (due to the risk of hypercalcemia and hypercalciuria).
- Severe heart, liver, or kidney failure.
- Ischemic heart disease.
- Arterial hypertension.
- Epilepsy or migraines.

### **Dosage and administration:**

The recommended dose is 5 g of gel (containing 50 mg of testosterone) applied once daily, preferably in the morning at approximately the same time.

The daily dose may be adjusted by the physician based on clinical and laboratory findings but should not exceed 10 g per day.

### **Dose adjustments:**

Doses should be adjusted stepwise in increments of 2.5 g of gel per day.

### **Application method:**

Apply the gel to clean, dry, undamaged skin of the shoulders, upper arms, and/or abdomen.

Avoid application to the genital area, as the high alcohol content may cause local irritation.

Allow the gel to dry for 3–5 minutes before dressing.

Wash hands thoroughly with soap after application.

### **Pump bottle usage:**

For the first use, fully prime the pump by pressing it five times. Discard the gel obtained from these presses.

Each subsequent press dispenses 1.25 g of gel, containing 12.5 mg of testosterone.

To achieve the prescribed daily dose, use the required number of presses as indicated below:

<b>Prescribed Daily Dose</b>	<b>Number of Presses</b>
50 mg	4
75 mg	6
100 mg	8

### **Side effects:**

#### **Most common (about 10%):**

Skin reactions at the application site, erythema, acne, and dry skin.

#### **Other reported side effects (>1/100, <1/10):**

Changes in laboratory test results (e.g., polycythemia, lipid changes).

Prostate changes, gynecomastia, mastodynia.

Dizziness, mood changes, or paresthesia.

### **Overdose:**

No cases of overdose with Androgel have been reported.

### **Use during pregnancy and lactation:**

Pregnant women should avoid any contact with the drug due to its potential virilizing effect on the fetus.

In case of contact, the affected area should be washed as soon as possible with soap and water.

### **Drug interactions:**

Androgel® should be used with caution with oral anticoagulants, as it may enhance their effects by altering hepatic synthesis of coagulation factors and competitively inhibiting plasma protein binding.

Prothrombin time should be monitored in patients on oral anticoagulants, particularly at the start or end of androgen therapy.

Co-administration of testosterone and ACTH or corticosteroids may increase the risk of edema.

### **Special instructions:**

Androgel® should only be used in cases of testosterone deficiency confirmed by clinical signs and laboratory tests.

Before initiating treatment, other possible causes of the symptoms should

be excluded.

There are no established age-specific testosterone norms. However, physiological testosterone levels begin to decline after the age of 30–40 years, with an associated increase in sex hormone-binding globulin levels.

Testosterone concentration should be measured consistently in the same laboratory.

**Storage conditions:**

Store at a temperature not exceeding 25°C.

Keep out of reach of children.

**Shelf life:**

3 years.

Do not use after the expiration date.

**Dispensing conditions:**

Prescription only.

**Manufacturer information:**

Besins Healthcare SA

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This instructions translated from official manufacturer instructions in Russian by [Extrapharma online pharmacy](#)