

**PATIENT LEAFLET IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Androgel 50 mg gel

Active ingredient and its quantity:
Testosterone 1% (50 mg/5 g)
For a list of inactive ingredients in the preparation – see section 6.
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for babies and children under the age of 18.

The medicine is not intended for women.

1. What is the medicine intended for?
The medicine is intended as a hormone replacement therapy in cases of testosterone deficiency.

Therapeutic class: Androgens.
2. Before using the medicine
❗ Do not use this medicine if:

- There is a known sensitivity to testosterone and/or any of the additional components the medicine contains (see section 6).
 - There is a diagnosis or a suspicion of prostate cancer or breast cancer.

❗ Before treatment with Androgel 50 mg, inform the doctor if:

- You are suffering from migraines and/or epilepsy. It should be used with caution, since it may worsen such conditions.
- You are suffering from high blood pressure or are treated with antihypertensive medicines, since testosterone may cause an increase in blood pressure.
- You are suffering from a serious heart, liver or kidney disease. Using Androgel 50 mg may cause severe complications related to fluid retention in the body, which may sometimes be accompanied by heart failure.

- You are suffering from breathing difficulties in your sleep. Breathing difficulties during sleep have been reported in people treated with Androgel, primarily in people who are overweight or who are suffering from breathing difficulties during sleep.
- You are suffering from cancer that affects the bones. Your blood and urine calcium levels may be higher than normal. Since Androgel 50 mg may have a similar effect with regard to blood and urine calcium level elevation, you may be asked to take blood and urine tests during treatment, in order to follow the calcium levels in your body.
- You are suffering or have suffered in the past from blood clotting problems.
- Thrombophilia (a condition of abnormal blood clotting, which increases the risk for thrombosis – blood clots in blood vessels).
- Factors that increase the risk for venous blood clots: a history of venous blood clots, smoking, weight gain, cancer, immobility, if someone from your immediate family has had a blood clot in the leg, lung or another organ at a young age (below the age of 50), age (the older you get).

How to recognize a blood clot: painful swelling in one leg or a sudden change in skin color, such as: pallor, redness or bluish discoloration, sudden shortness of breath, sudden, unexplained cough which may bring up blood or sudden chest pain, fainting sensation or severe dizziness, severe abdominal pain, sudden loss of vision. **If you experience any of these symptoms, seek medical attention immediately.**

❗ Tests that should be performed before using the medicine

- Before starting to use Androgel 50 mg, testosterone deficiency should be confirmed by measurement of testosterone blood level in two separate blood tests performed in the same lab, and by obvious clinical characteristics (such as: withdrawal of masculine characteristics, decrease in lean body mass (muscle mass), weakness or fatigue, decreased libido, inability to achieve erection or maintain an erection, etc.)

❗ It is not recommended to use Androgel 50 mg:

- In children, since no clinical data is available for children under 18.
- In women, due to the risk of developing male-like features.

❗ Additional warnings

- Androgens may increase the risk for enlarged prostate (benign prostate hypertrophy) or for prostate cancer. In accordance with the doctor's recommendation, regular examinations of the prostate should be performed before and during the treatment.
- Blood tests (testosterone blood level and complete blood count) should be performed before and during treatment.
- A long-term testosterone replacement therapy may cause abnormal increase in the number of red blood cells (polycythaemia); therefore, you should perform regular blood tests during treatment with Androgel 50 mg.
- If you are suffering from severe skin reactions, the treatment should be evaluated and discontinued if necessary.
- The following symptoms may indicate that the dosage you are taking is too high: restlessness, agitation, weight gain, frequent or prolonged erection. Report any of these symptoms to the doctor to have your dosage adjusted.

❗ Possible transfer of testosterone
Testosterone may be absorbed by another person following a close and relatively prolonged physical contact with the area to which the gel was applied, unless that area is covered.

This may cause your partner to develop signs of increased testosterone level, such as: excessive hair growth on the face and body, low and deep voice, menstrual changes in women.

Wearing clothes that cover the area to which the gel was applied or washing that area with soap and water (shower) before contact protect against possible transfer of testosterone.

It is recommended to adhere to the following precautions:

1. Wash your hands with soap and water after applying the gel.
2. Cover the applied area with clothes after it has dried.

3. Wash the applied area before coming in close contact with another person.

If there is a concern that testosterone has transferred to another person (woman or child):

1. Immediately wash the contact area with soap and water.
2. Inform the doctor if signs such as acne, growth changes and changes in body or face hair growth pattern occur.

It is advisable to wait at least one hour between the time of applying the gel and taking a bath or a shower.

❗ Drug-drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. The doctor may adjust your dosage of Androgel 50 mg on account of taking these medicines. Especially inform the doctor or pharmacist if you are taking:

- Anticoagulants (blood thinners).
- Insulin (for treatment of Diabetes).
- Corticosteroids (anti-inflammatory medicines).

❗ Pregnancy and breastfeeding
• Androgel 50 mg should not be used in pregnant or breastfeeding women.
• Pregnant women should avoid **any** contact with areas to which the product was applied. This medicine may lead to development of unwanted male-like features in the developing fetus. In case of contact with the product, wash the contact area as soon as possible with soap and water, as recommended above. If your partner has become pregnant, you **must** adhere to the instructions regarding prevention of testosterone gel transfer.

❗ Driving and operating machinery
Androgel 50 mg does not affect the ability to drive or operate machinery.

❗ Smoking
Do not light a cigarette or expose yourself to fire before the preparation has completely dried.

❗ Attention athletes and women: this medicine contains the active substance testosterone, which may cause athletes to test positive during drug testing.

❗ Important information about some ingredients of the medicine
The preparation contains 3.6 grams of alcohol

(ethanol) in each sachet, which may cause a burning sensation on damaged skin. The preparation is flammable so long as it is not dry.

3. How should you use the medicine?
The medicine is intended for treatment of adult men only.

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is 5 grams of gel (50 mg testosterone) for application once a day at the same time each day, preferably in the morning hours. The doctor may change the dosage, but a dose of 10 grams of gel per day should not be exceeded.

The dosage adjustment, if necessary, should be achieved by 2.5 g of gel steps. In Israel, this dose is registered for another product. **Do not exceed the recommended dose.** A thin layer of gel should be applied to the area of the shoulders, arms or abdomen when the skin is dry, clean and healthy.

The entire contents of the packet should be applied to the skin immediately after opening the packet.

Wait for at least 3-5 minutes until the gel dries. Then you can get dressed. Wash your hands with soap and water after you have finished applying the gel.

Do not apply the gel to the genitals area, since the high percentage of alcohol in the product may cause local irritation.

Do not light a cigarette or expose yourself to fire before the preparation has completely dried.

Do not swallow. For external use only.

Tests and follow-up
Before starting to use the medicine, the doctor will refer you to extensive medical examinations. During treatment, you will also be referred to periodic medical examinations (at least once a year or twice a year in the elderly population or in at-risk population). **If you have accidentally applied a higher dosage** the following signs may appear: restlessness, agitation, weight gain, frequent and prolonged erection.

You should consult with the doctor. If you took an overdose or a child accidentally

swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to apply the gel at the required time, do not apply a double dose. Apply the regular dose at the regular time and consult a doctor.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Androgel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Very common side effects - side effects that occur in more than one out of 10 users: Due to the alcohol content of the product, frequent use of the product may cause irritation and dryness of the skin. In addition, acne may appear.

Common side effects - occurring in 1-10 out of 100 users:

- Headaches
- Hair loss
- Development of sensitivity and pain in the breasts, enlarged breasts
- Changes in the prostate
- Diarrhea
- Dizziness
- Blood pressure elevation
- Mood changes
- Hematocrit (percent of red blood cells in the blood) and hemoglobin values elevation, changes in lipid levels
- Skin hypersensitivity, itching
- Memory loss

Additional side effects observed with oral or injected testosterone:

- Weight gain
- Changes in blood salts levels
- Muscle pains
- Agitation, depression, hostility
- Breathing difficulties during sleep
- Yellowing of the skin (jaundice)
- Changes in liver tests results
- Seborrhea

- Changes in libido, decrease in the amount of semen, frequent or prolonged erection
- Difficulties in urination, fluid retention
- Hypersensitivity reactions

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor. Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor!
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.

6. Additional information:

- In addition to the active ingredient the medicine also contains: Purified water, Ethanol 96%, Sodium hydroxide, Carbomer 980, Isopropyl myristate
- What does the medicine look like and what are the contents of the package: The package contains 30 packets of 5 grams of clear and colorless gel.
- License holder/importer and the address: CTS Ltd., 4 Haharash St., Hod Hasharon.
- Name and address of the manufacturer: Besins International Laboratories, 3 Rue du Bourg L'abbé 75003, Paris, France
- This leaflet was revised in 01/2021 according to MOHs guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1411830760