

Patient Package Insert according to Pharmacists’ Regulations (Preparations)-1986

This medicine can be sold with a doctor's prescription only

TESTOMAX 25 mg Gel

TESTOMAX 50 mg Gel

Active ingredient and its quantity:

Each 2.5 gram sachet contains: Testosterone 25 mg

Each 5 gram sachet contains: Testosterone 50 mg

Inactive ingredients and allergens in the medicine - see section 2 “**Important information about some of the ingredients of this medicine**” and section 6 in the leaflet.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

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

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

This medicine is not intended for women.

1. What is the medicine intended for?

The medicine is intended as a hormone replacement therapy in males in cases of testosterone deficiency (hypogonadism), which has been confirmed by clinical features and laboratory tests.

Therapeutic group: Androgens.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients this medicine contains (for a list of the inactive ingredients see section 6).
- there is a diagnosis or a suspicion of prostate cancer or breast cancer.

Special warnings regarding the use of this medicine

Before treatment with Testomax, tell the doctor if:

- You suffer from a migraine and/or epilepsy. It should be used with caution since it may worsen these conditions.
- you suffer from high blood pressure or you are treated with antihypertensive medicines, since testosterone may cause an increase in blood pressure.
- you suffer from a severe heart, liver or kidney disease. Using Testomax may cause severe complications related to fluid retention in the body, which sometimes are accompanied by heart failure.
- you suffer from breathing difficulties while sleeping. Breathing difficulties during sleep have been reported in people treated with Testomax, primarily in people who are overweight or who suffer from breathing difficulties during sleep.
- you suffer from cancer that affects the bones. Your blood and urine calcium levels may be higher than usual. Since Testomax may have a similar effect with regard to blood and urine calcium levels elevation, you may be asked to have blood and urine tests during treatment, in order to follow the calcium levels in your body.
- you suffer 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)].
- there are factors that increase the risk of blood clots in the veins: past blood clots in the veins, smoking, weight gain, cancer, lack of movement, a blood clot at a young age (under the age of 50) in the leg, in the lung or in another organ in a member of your immediate family, age (as one gets older).

How to identify a blood clot: painful swelling in one of the legs or a sudden change in skin color such as: pallor, redness or turning blue, sudden shortness of breath, sudden unexplained cough which may be bloody or sudden chest pain, feeling faint or severe dizziness, severe pain in the abdomen, sudden loss of vision. **Seek medical attention immediately if you experience one of these symptoms.**

Tests that should be performed before using the medicine

- Before starting to use Testomax, testosterone deficiency should be confirmed by measuring testosterone blood level using 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 tiredness, decreased libido, inability to achieve erection or maintain an erection, etc.}.

It is not recommended to use Testomax:

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

Additional warnings:

- Androgens may increase the risk for an enlarged prostate (benign prostate hypertrophy) or for prostate cancer. In accordance with the doctor's recommendation, regular prostate tests should be performed before and during the treatment.
- Blood tests (testosterone blood level and complete blood count) should be performed before and during treatment.
- 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 Testomax.
- If you suffer 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 protects 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 area where the gel was applied before 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 are observed.

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

Smoking

Do not light a cigarette or be exposed to fire until the medicine has completely dried.

For the attention of athletes and women: this medicine contains the active ingredient testosterone which may yield a positive result in drug testing performed in athletes.

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).

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

The doctor may adjust your dosage of Testomax on account of taking these medicines. Especially inform the doctor or pharmacist if you are taking:

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

Pregnancy and breastfeeding

- Do not use Testomax 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, as

recommended above, wash the contact area as soon as possible with soap and water. If your partner has become pregnant, you **must** adhere to the instructions regarding prevention of testosterone gel transfer.

Driving and using machinery

Testomax does not affect the ability to drive or operate machinery.

Important information about some of the ingredients of this medicine

This medicine contains approximately 3.35 mg alcohol per each 5-gram sachet and 1.68 mg alcohol per each 2.5-gram sachet.

This may cause a burning sensation on damaged skin.

3. How to use this 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 not sure about the dosage and the manner of treatment with the medicine. The usual recommended dosage is 5 grams of gel (50 mg testosterone) applied once a day, at a fixed time, preferably in the morning hours. The doctor may change the dosage, but a dose of 10 g of gel per day should not be exceeded.

Do not exceed the recommended dose.

Instructions for opening:

- Tear the sachet along the line.
- Squeeze the sachet from the bottom to the top so all of the gel comes out into the palm of your hand and apply to the designated areas. You may also apply the gel from the sachet directly to the designated areas.
- Apply a thin layer of the gel to the area of the shoulders, arms or abdomen when the skin is dry, clean and healthy.
- Apply the entire contents of the sachet immediately after its opening.
- Wait at least 3-5 minutes until the gel dries and then you can get dressed.
- Wash your hands with water and soap immediately after 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 be exposed to fire until the product has been completely dried.

Do not swallow.

For external use only.

If you have accidentally applied a higher dosage the following signs may appear: restlessness, agitation, weight gain, frequent and prolonged erection. You should consult the doctor.

If you applied an overdose or if a child or anyone else accidentally swallowed this medicine, immediately contact your doctor or go to a hospital emergency room and bring the package of the medicine with you

If you forgot to apply the gel at the designated time, do not apply a double dose. Apply the regular quantity at the regular time and consult the doctor. Follow the treatment as recommended by the doctor.

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

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

4. Side effects

As with any medicine, the use of Testomax may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Very common side effects - appear 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 - appear in 1-10 out of 100 users: Headache, hair loss, development of breast pain and tenderness, 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, tingling, memory loss.

Additional side effects observed with oral or injected testosterone:

Weight gain, changes in blood salts levels, muscles pain, agitation, depression, hostility, breathing disorders during sleep, yellowing of the skin (jaundice), changes in liver test 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 appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult a doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Report adverse effects and problems associated with medications” that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>.

Additionally, side effects can be reported to Padagis via the following address:

padagis.co.il

5. How to store the medicine

- Avoid poisoning! This medicine and all other medicines must be stored 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. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in the original package below 25°C.
- Caution! Inflammable substance, keep away from fire.

6. Additional information

• In addition to the active ingredient, the medicine also contains:

Dehydrated alcohol, purified water, carbomer homopolymer type C, isostearic acid, sodium hydroxide.

• What the medicine looks like and contents of the package:

Testomax 25 mg: the package contains 30 aluminum sachets of 2.5 grams of clear, colorless gel.

Testomax 50 mg: the package contains 30 aluminum sachets of 5 grams of clear, colorless gel.

• Manufacturer and Registration Holder: Padagis Israel Pharmaceuticals Ltd., Rakefet 1 St., Shoham.

• Revised in March 2022 according to the MOH guidelines.

• Drug registration numbers at the national medicines registry of the Ministry of Health:

Testomax 25 mg: 136-20-31297

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