CONTRAINDICATIONS

Who should not use testosterone gel 1.62%?

Testosterone gel 1.62% is a controlled substance (CIII) because:

• are pregnant or may become pregnant or are breastfeeding.
• have or might have prostate cancer.
• have kidney or liver problems.
• have heart problems.
• use corticosteroids.
• have early development of pubic hair.
• have not had sex with another person in the past 5 years.

Stop using testosterone gel 1.62% and call your healthcare provider if you:

• feel less strong or less interested in sex.
• have swelling of the body.
• have redness or irritation at the application site.
• have trouble sleeping or feel nervous, irritable, or depressed.

• have urinary incontinence or are frequently wakening to pass urine during the night.
• have a change in the amount or frequency of urination.
• have to rush to get to the bathroom.
• have trouble starting your urine stream.
• have a change in your blood pressure.

• have an increase in your body or facial hair.

• have one or more of the following symptoms:
  • early development of pubic hair
  • increased erections and libido
  • aggressive behavior
  • advanced bone age

The following adverse reactions have also been reported in men: transient ischemic attacks, convulsions, hypomania, depression, suicidal thoughts or behavior, aggressiveness, irritability, mood swings, acne, hirsutism, erectile dysfunction, testicular atrophy, breast tenderness, and gynecomastia.

Adverse reactions for women include: breast tenderness, breast enlargement, swelling of the breasts, menstrual cycle changes, and changes in sexual desire.

Testosterone gel 1.62% may harm your unborn or breastfeeding infant. Testosterone gel 1.62% can pass into breast milk. You should not use this medicine if you are pregnant or breastfeeding. If you become pregnant while using this medicine, call your healthcare provider right away. Do not use this medicine if you are nursing a baby.

Effect of sunscreen or moisturizing lotion on absorption of testosterone

In a randomized, open-label, single-dose, 2-way crossover study in 16 healthy male subjects, the effect of hand washing on the absorption of testosterone was studied. The mean testosterone Cavg and Cmax in female subjects on day 7 increased by 60% and 57.8% respectively, following hand washing.

If you have any questions about or are concerned about your condition, please consult your healthcare provider. They will be able to provide you with information about the benefits and risks of this medicine.

IMPORTANT SAFETY INFORMATION

Before you start using testosterone gel 1.62%, read the first page of the full prescribing information. (2)

WARNING: Fewer than 1% of people using testosterone have experienced testicular pain, swelling, or tenderness. If this occurs, call your healthcare provider right away. If you have one or more of the following symptoms:

• testicular pain, swelling, or tenderness
• a lump in the testicle
• a testicle that feels softer than other testicles
• a testicle that does not feel normal
• changes in the size or shape of the testicles
• testicular pain when you have sex
• testicular pain after you start using testosterone gel 1.62%

• do not use testosterone gel 1.62% and call your healthcare provider right away.

Testosterone can cause prostate enlargement that may lead to uncomfortable or painful symptoms such as:

• difficulty urinating
• a weak or interrupted urine stream
• the need to get up several times during the night to pass urine
• an inability to start or stop urination
• a difficult feeling when urinating

• if you have any of these symptoms, call your healthcare provider right away.

Most adverse reactions reported by patients using testosterone products were not serious and did not require discontinuation of treatment. Many of these reactions occurred within the first month of using testosterone products.

The estimated major adverse effects in patients using testosterone products were:

• an increase in prostate size
• an increase in prostate specific antigen (PSA) levels

Testosterone products are not recommended for use in men who have prostate cancer.

Testosterone products are not recommended for use in women who are pregnant or may become pregnant or are breastfeeding.

Testosterone products are not recommended for use in children.

Testosterone products are not recommended for use in patients with a history of prostate cancer.

Testosterone products are not recommended for use in patients with a history of liver disease.

Testosterone products are not recommended for use in patients with a history of cardiovascular disease.

Testosterone products are not recommended for use in patients with a history of endocrine disease.

Testosterone products are not recommended for use in patients with a history of kidney disease.

Testosterone products are not recommended for use in patients with a history of respiratory disease.

Testosterone products are not recommended for use in patients with a history of psychiatric disease.

Testosterone products are not recommended for use in patients with a history of drug or alcohol abuse.

Testosterone products are not recommended for use in patients with a history of substance abuse.

Testosterone products are not recommended for use in patients with a history of seizure disorders.

Testosterone products are not recommended for use in patients with a history of autoimmune disease.

Testosterone products are not recommended for use in patients with a history of connective tissue disease.

Testosterone products are not recommended for use in patients with a history of infectious disease.

Testosterone products are not recommended for use in patients with a history of prostatic disease.

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What are the ingredients in testosterone gel 1.62%?

For more information, contact Teva Pharmaceuticals USA, Inc. about testosterone gel 1.62%. If you would like more information, talk to your healthcare provider or pharmacist.

1.62% to other people, even if they have the same symptoms you have.

Medicines are sometimes prescribed for purposes other than those

For more information, ask your healthcare provider or pharmacist.

17.1 Steady-State Levels of Total Testosterone

• The possibility of secondary exposure to testosterone gel should be brought to the attention of a healthcare provider.

17.3 Potential Adverse Reactions with Androgens

• Patients using testosterone gel 1.62% should apply the product as directed and strictly adhere to the following:

Children and women should avoid contact with unwashed or unclothed application site(s): 

• Wait 2 hours before swimming or washing following application of testosterone gel 1.62%. This will ensure that the greatest amount of testosterone gel 1.62% is absorbed into their system.

Testosterone gel 1.62% should be applied and used appropriately to maximize the benefits and to minimize the risk of secondary exposure in children and women.

• It is important to adhere to all recommended monitoring.

• Have symptoms breathing while you sleep (sleep apnea).

• Enlarged or painful breasts.

• Increased red blood cell count.

• Increased prostate specific antigen (a test used to screen for prostate cancer)

• The most common side effects of testosterone gel 1.62% include:

• Increased prostate specific antigen (a test used to screen for prostate cancer)

• Risk of secondary exposure to testosterone gel 1.62% is reduced when testosterone gel 1.62% is used on the skin of men who are not at risk of secondary exposure (e.g., if there is no risk of pregnancy for the woman who could become pregnant and the woman is not pregnant).

• In the event that unwashed or unclothed skin to which testosterone gel 1.62% has been applied comes in contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible.

• Avoid contact with the eyes, mouth, or broken skin.

• Avoid contact with children or pets.

• A woman should not handle testosterone gel 1.62% until the skin is dry.

• Use of testosterone gel 1.62% by children and women is contraindicated.

• Consider placing children and pets in an area where testosterone gel 1.62% cannot be accessed.

• Testosterone gel 1.62% should not be applied to the skin near the eye(s) or mouth as this could lead to a risk of secondary exposure.

• Testosterone gel 1.62% contains alcohol, isopropyl myristate, purified water and sodium hydroxide.

• For more information, contact Teva Pharmaceuticals USA, Inc. about testosterone gel 1.62%. If you would like more information, talk to your healthcare provider or pharmacist.

• Direct contact should be made with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible.

• Avoid placing children and pets in an area where testosterone gel 1.62% cannot be accessed.

• Avoid placing in an area where children and pets can access testosterone gel 1.62% (e.g., in a child's diaper bag, purse, or a pet's dish).