INDICATION

What are FORTESTA® (testosterone) Gel and Testosterone Gel? 
FORTESTA® Gel and Testosterone Gel are prescription medications that contain testosterone. They are used to treat adult males who have low or no testosterone due to certain medical conditions. Your healthcare provider will test your blood before you start taking and while you are taking FORTESTA® Gel or Testosterone Gel.

It is not known if FORTESTA® Gel and Testosterone Gel are safe or effective to treat men who have low testosterone due to aging.

It is not known if FORTESTA® Gel and Testosterone Gel are safe or effective in children younger than 18 years old. Improper use of FORTESTA® Gel and Testosterone Gel may affect bone growth in children.

FORTESTA® Gel and Testosterone Gel are controlled substances (CIII) because they contain testosterone that can be a target for people who abuse prescription medicines.

Keep your FORTESTA® Gel or Testosterone Gel in a safe place to protect it. Never give FORTESTA® Gel or Testosterone Gel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

FORTESTA® Gel and Testosterone Gel are not meant for use in women.

IMPORTANT SAFETY INFORMATION about FORTESTA® Gel and Testosterone Gel

What is the most important information I should know about FORTESTA® Gel and Testosterone Gel?

- FORTESTA® Gel and Testosterone Gel can transfer from your body to others. This can happen if other people come into contact with the area where the FORTESTA® Gel or Testosterone Gel was applied.

Please see Important Safety Information continued on next page.

Please click here for full Prescribing Information, including the Medication Guide for patients for FORTESTA® Gel.

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Could it be Low T?

Low T is another term for low testosterone, which is also called male hypogonadism. All men naturally lose some testosterone over time. However, some men lose more than they should.

Ask your healthcare professional:
- Should I have my testosterone level checked?
- Is 2% FORTESTA® Gel or Testosterone Gel right for me?

Results from a clinical study showed that 2% FORTESTA® Gel and Testosterone Gel were effective for a majority of men who were treated for Low T.

The most common side effects of 2% FORTESTA® Gel and Testosterone Gel include skin redness or irritation where FORTESTA® Gel or Testosterone Gel is applied, increased PSA (prostate specific antigen) levels in the blood (which are used to screen for prostate cancer), and abnormal dreams.

IMPORTANT SAFETY INFORMATION about FORTESTA® Gel and Testosterone Gel (cont’d)

- Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through contact with men using topical testosterone products like FORTESTA® Gel and Testosterone Gel
  - Women and children should avoid contact with the unwashed or unclothed areas where FORTESTA® Gel or Testosterone Gel have been applied. If a woman or child makes contact with the FORTESTA® Gel or Testosterone Gel application area, that area on the woman or child should be washed well with soap and water right away
  - To lower the risk of transfer of FORTESTA® Gel or Testosterone Gel from your body to others, you should: Apply FORTESTA® Gel or Testosterone Gel only to the front and inside area of your thighs that will be covered by clothing and wash your hands right away with soap and water after applying FORTESTA® Gel or Testosterone Gel. After the gel has dried, cover the application area with clothing and keep the area covered until you have washed the application area well or have showered

Why ask your healthcare professional about 2% FORTESTA® (testosterone) Gel and Testosterone Gel?

Treatment with 2% FORTESTA® Gel and Testosterone Gel is:

- Colorless and odorless, applied with one finger
  - The most common adverse reaction is skin redness or irritation where FORTESTA® Gel or Testosterone Gel is applied

- Quick to dry – dried quickly (in less than 2½ minutes) after application in a study of men with Low T
  - Avoid swimming, showering, or bathing for at least 2 hours after you apply FORTESTA® Gel or Testosterone Gel
  - FORTESTA® Gel and Testosterone Gel are flammable until dry. Let FORTESTA® Gel or Testosterone Gel dry before smoking or going near an open flame

- Low volume – 2% concentration of testosterone, so a small amount may be all you need
  - Your healthcare provider may change your FORTESTA® Gel or Testosterone Gel dose. Do not change your FORTESTA® Gel or Testosterone Gel dose without talking to your healthcare provider

- Available in a small, travel-size canister
  - When it is time to throw away the canister, safely throw away used FORTESTA® Gel and Testosterone Gel in household trash. Be careful to prevent accidental exposure of children or pets

If you’re just starting a Low T treatment, or looking to return to one, ask your healthcare professional if 2% FORTESTA® Gel and Testosterone Gel are right for you.
One-finger application

1 APPLY to thigh and rub on with one finger
No applicator required. Pump the gel directly onto the clean, dry, and intact skin of each front and inner thigh. Gently rub 2% FORTESTA® (testosterone) Gel or Testosterone Gel evenly onto the front and inner area of each thigh using one finger.

2 WASH hands thoroughly
Wash thoroughly with soap and water right away.

3 ALLOW sites to dry and cover with clothing
Let the application sites dry for a few minutes, and then cover with clothing.

Application tips

Before you apply, keep in mind:
• Your healthcare professional will tell you how much 2% FORTESTA® Gel and Testosterone Gel to use and when to apply it. It’s important that you do exactly as instructed
• The metered pump will help you apply the precise dose; rub it on with one finger

Before your first use, prime the canister to ensure that a proper, full dose is dispensed. To prime, push down on the pump 8 times over a sink, then safely wash away any gel you dispensed.

Important things to remember
• Avoid swimming, showering, or bathing for a minimum of 2 hours after application
• FORTESTA® Gel and Testosterone Gel are flammable until dry, so avoid fire, flames, or smoking after application
• Do not apply FORTESTA® Gel and Testosterone Gel to the genitals, stomach area, shoulders, or upper arms

IMPORTANT SAFETY INFORMATION about FORTESTA® Gel and Testosterone Gel (cont’d)
— If you expect another person to have skin-to-skin contact with your thighs, first wash the application area well with soap and water
• Stop using FORTESTA® Gel or Testosterone Gel and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to FORTESTA® Gel or Testosterone Gel
• Do not use FORTESTA® Gel or Testosterone Gel if you have breast cancer, have or might have prostate cancer, are pregnant, may become pregnant, or are breastfeeding
  — FORTESTA® Gel and Testosterone Gel may harm your unborn or breastfeeding baby. Women who are or who may become pregnant should avoid contact with the area of skin where FORTESTA® Gel or Testosterone Gel have been applied
• Your doctor may check your testosterone, prostate specific antigen (PSA), blood count, liver function, cholesterol, and blood calcium levels while taking FORTESTA® Gel or Testosterone Gel

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Follow up with your healthcare professional to find the right dose

Symptoms of Low T can occur when your testosterone level is below normal range. Testosterone replacement therapy may help raise your testosterone level, but only a blood test can tell you if you’re just below normal, just above it, or just where you need to be.

Your healthcare professional may periodically order a blood test to recheck your T level. This will help find the dose that provides just the right amount of testosterone to meet your individual needs.

IMPORTANT SAFETY INFORMATION about FORTESTA® Gel and Testosterone Gel (cont’d)

Other possible serious side effects include:
• If you already have enlargement of your prostate gland, your signs and symptoms can get worse while using FORTESTA® Gel or Testosterone Gel
• Possible increased risk of prostate cancer
• Blood clots in the legs or lungs. This can include pain, swelling or redness of your legs, difficulty breathing, or chest pain
• Possible increased risk of heart attack, death or stroke
• In large doses FORTESTA® Gel and Testosterone Gel may lower your sperm count
• Swelling of your ankles, feet, or body, with or without heart failure. This may cause serious problems for people who have heart, kidney, or liver disease
• Enlarged or painful breasts
• Problems breathing while you sleep (sleep apnea)
• Increased red blood cell count
• FORTESTA® Gel and Testosterone Gel may cause an increase in blood calcium levels in some patients with cancer
• FORTESTA® Gel and Testosterone Gel are flammable until dry. Let FORTESTA® Gel and Testosterone Gel dry before smoking or going near an open flame

Call your healthcare provider right away if you have any of the serious side effects listed above.

Tell your healthcare provider about all of your medications, especially insulin, medicines that decrease blood clotting, and corticosteroids.

The most common side effects of FORTESTA® Gel and Testosterone Gel include skin redness or irritation where FORTESTA® Gel or Testosterone Gel is applied, increased prostate specific antigen (PSA) (a test used to screen for prostate cancer), and abnormal dreams.

Other side effects include more erections than are normal for you or erections that last for a long time.

Drug abuse is intentional use of a drug, even once, for its rewarding psychological and physiological effects.

Physical dependence can result in withdrawal symptoms after abrupt drug discontinuation or a significant dose reduction of a drug. Individuals taking very high doses of testosterone may experience withdrawal symptoms lasting for weeks or months which include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido and hypogonadotropic hypogonadism.

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— If you expect another person to have skin-to-skin contact with your thighs, first wash the application area well with soap and water.

• Do not use FORTESTA® Gel or Testosterone Gel if you have breast cancer, have or might have prostate cancer, are pregnant, or are breastfeeding.

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• Your doctor may check your testosterone, prostate specific antigen (PSA), blood count, liver function, cholesterol, and blood calcium levels while taking FORTESTA® Gel or Testosterone Gel.

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• Possible increased risk of prostate cancer.

• Blood clots in the legs or lungs. This can include pain, swelling or redness of your legs, difficulty breathing, or chest pain.

• Possible increased risk of heart attack, death or stroke.

• In large doses FORTESTA® Gel and Testosterone Gel may lower your sperm count.

• Swelling of your ankles, feet, or body, with or without heart failure. This may cause serious problems for people who have heart, kidney, or liver disease.

• Enlarged or painful breasts.

• Problems breathing while you sleep (sleep apnea).

• Increased red blood cell count.

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Physical dependence can result in withdrawal symptoms after abrupt drug discontinuation or a significant dose reduction of a drug. Individuals taking very high doses of testosterone may experience withdrawal symptoms lasting for weeks or months which include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido and hypogonadotropic hypogonadism.

Serious side effects associated with abuse of testosterone and anabolic androgenic steroids include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility and aggression.

Side effects associated with abuse or misuse by men include mini-stroke, convulsions, mild mania (elation and hyperactivity), irritability, abnormal blood lipids, decrease in size or function of testicles, decreased or absence of fertility.

Side effects associated with abuse or misuse by women include unwanted hair growth, development of male characteristics, voice deepening, clitoris enlargement, decrease in size or function of breasts, male pattern baldness, menstrual irregularities.

Side effects associated with abuse or misuse by male and female adolescents include halting of growth and early puberty.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FORTESTA® Gel and Testosterone Gel. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

THE SAME FORMULATION IS AVAILABLE AS AN AUTHORIZED GENERIC

The low volume, apply-to-thigh, allow-to-dry, 2% Testosterone Gel that patients can rub on with just one finger.

An authorized generic may offer a lower co-pay, so make sure your prescription for 2% FORTESTA® Gel includes Substitution Permissible

- Pharmacist can substitute Authorized Generic for 2% FORTESTA® Gel

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.