
MEDICATION GUIDE

FORTESTA™ (FOR-tes-ta) CIII

(testosterone) Gel

Read this Medication Guide before you start using FORTESTA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about FORTESTA?

FORTESTA can transfer from your body to others. This can happen if other people come into contact with the area where the FORTESTA was applied.

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.

- **Women and children should avoid contact with the unwashed or unclothed area where FORTESTA has been applied. If a woman or child makes contact with the FORTESTA 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 from your body to others, you should follow these important instructions:
 - Apply FORTESTA **only** to the front and inside area of your thighs that will be covered by clothing.
 - Wash your hands **right away** with soap and water after applying FORTESTA.
 - After the FORTESTA gel has dried, **cover the application area with clothing**. Keep the area covered until you have washed the application area well or have showered.
 - **If you expect another person to have skin-to-skin contact with your thigh, first wash the application area well with soap and water.**

Stop using FORTESTA 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:

Signs and symptoms in **children** may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms in **women** may include:

- changes in body hair

- a large increase in acne

What is FORTESTA?

FORTESTA is a prescription medicine that contains testosterone. FORTESTA is used to treat adult males who have low or no testosterone.

Your healthcare provider will test your blood before you start taking and while you are taking FORTESTA.

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

FORTESTA is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your FORTESTA in a safe place to protect it. Never give FORTESTA 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 is not meant for use in women.

Who should not use FORTESTA?

Do not use FORTESTA if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or breast-feeding. FORTESTA may harm your unborn or breast-feeding baby.

Women who are pregnant or who may become pregnant should avoid contact with the area of skin where FORTESTA has been applied.

Talk to your healthcare provider before taking this medicine if you have any of the above conditions.

What should I tell my healthcare provider before using FORTESTA?

Before you use FORTESTA, tell your healthcare provider if you:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have liver or kidney problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using FORTESTA with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting
- corticosteroids

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use FORTESTA?

- It is important that you apply FORTESTA exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much FORTESTA to apply and when to apply it.
- Your healthcare provider may change your FORTESTA dose. Do not change your FORTESTA dose without talking to your healthcare provider.
- **FORTESTA should be applied to the front and inner part of your thighs only.** Do not apply FORTESTA to any other parts of your body such as your stomach area (abdomen), penis, scrotum, shoulders or upper arms.
- Apply FORTESTA in the morning. If you shower or bathe, FORTESTA should be applied afterwards.
- Avoid swimming, showering, or bathing for at least 2 hours after you apply FORTESTA.
- **FORTESTA is flammable until dry. Let FORTESTA dry before smoking or going near an open flame.**
- **Apply FORTESTA only to areas that will be covered by shorts or pants.**
- **Wash your hands with soap and water right after you apply FORTESTA.**

Applying FORTESTA:

- Before using a new canister of FORTESTA for the first time, you will need to prime the pump. To prime the FORTESTA pump, gently push down on the pump 8 times. Do not use any FORTESTA that comes out while priming. Wash it down the sink or throw it in the trash to avoid accidental exposure to others. Your FORTESTA pump is now ready to use.
- **Use FORTESTA exactly as your healthcare provider tells you to use it.** Your healthcare provider will tell you the dose of FORTESTA that is right for you.
- Depress the pump to apply the medicine directly on clean, dry, intact skin of the front and inner part of your thighs. Use one finger to gently rub FORTESTA evenly onto the front and inner part of each thigh.

Recommended Application Area



Do not apply FORTESTA to your penis or scrotum.

- Let the application site dry completely before putting on shorts or pants.
- **Wash your hands right away with soap and water.**

What are the possible side effects of FORTESTA?

See “**What is the most important information I should know about FORTESTA?**”

FORTESTA can cause serious side effects including:

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse** while using FORTESTA. This can include:
 - increased urination at night
 - trouble starting your urine stream
 - having to pass urine many times during the day
 - having an urge that you have to go to the bathroom right away
 - having a urine accident
 - being unable to pass urine or weak urine flow
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use FORTESTA.
- **In large doses FORTESTA may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Have problems breathing while you sleep (sleep apnea).**
- **Increased red blood cell count**
- **Blood clots in the legs.** This can include pain, swelling or redness of your legs.
- **Call your healthcare provider right away if you have any of the serious side effects listed above.**
- **The most common side effects of FORTESTA include:**
 - skin redness or irritation where FORTESTA is applied

- increased in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer)
- abnormal dreams

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

Tell your healthcare provider 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. 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.

How should I store FORTESTA?

- Store FORTESTA at 15°C to 30°C (59°F to 86°F).
- When it is time to throw away the canister, safely throw away used FORTESTA in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep FORTESTA away from fire.
- Do not freeze FORTESTA.

Keep FORTESTA and all medicines out of the reach of children.

General information about FORTESTA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FORTESTA for a condition for which it was not prescribed. Do not give FORTESTA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about FORTESTA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about FORTESTA that is written for health professionals.

For more information, go to www.FORTESTA.com or call 1-800-462-3636.

What are the ingredients in FORTESTA?

Active ingredient: testosterone

Inactive ingredients: propylene glycol, purified water, ethanol, 2-propanol, oleic acid, carbomer 1382, triethanolamine and butylated hydroxytoluene.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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