

MEDICATION GUIDE
FORTESTA® (FOR-tes-ta) CIII
(testosterone)
Gel for topical use

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

- 1. FORTESTA can transfer from your body to others including, children and women.** Children and women should avoid contact with the unwashed or not covered (unclothed) areas where FORTESTA has been applied to your skin. Early signs and symptoms of puberty have occurred in young children who have come in direct contact with testosterone by touching areas where men have used FORTESTA.

Children

Signs and symptoms of early puberty in a child when they come in direct contact with FORTESTA may include:

Abnormal sexual changes:

- enlarged penis or clitoris.
- early growth of hair near the vagina or around the penis (pubic hair).
- erections or acting out sexual urges (sex drive).

Behavior problems:

- acting aggressively, behaving in an angry or violent way.

Women

Signs and symptoms in women when they come in direct contact with FORTESTA may include:

- changes in body hair.
- an abnormal increase in pimples (acne).

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 happened through accidental touching of the area where you have applied FORTESTA.

- 2. To lower the risk of transfer of FORTESTA from your body to others, 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 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 to have skin-to-skin contact with another person, first wash the application area well with soap and water.
- If a child or woman touches the area where you have applied FORTESTA, that area on the child or woman should be washed well with soap and water right away.

What is FORTESTA?

FORTESTA is a prescription medicine that contains testosterone. FORTESTA is 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 and while you are using FORTESTA.

- It is not known if FORTESTA is safe or effective to treat men who have low testosterone due to aging.
- 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.

Do not use FORTESTA if you:

- have breast cancer.
- have or might have prostate cancer.
- are pregnant. FORTESTA may harm your unborn baby.
- Women who are pregnant should avoid contact with the area of skin where FORTESTA has been applied.

Before using FORTESTA, tell your healthcare provider about all of your medical conditions including 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).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 (blood thinners)
- corticosteroids

How should I use FORTESTA?

- See the detailed **Instructions for Use** for information about how to use FORTESTA at the end of this Medication Guide.
- It is important that you apply FORTESTA exactly as your healthcare provider tells you to.
- Your healthcare provider may change your FORTESTA dose. **Do not** change your FORTESTA dose without talking to your healthcare provider.
- Apply FORTESTA in the morning. If you shower or bathe, FORTESTA should be applied afterwards.

What are the possible side effects of FORTESTA?

FORTESTA can cause serious side effects including:

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

- **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 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.
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include leg pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Possible increased risk of heart attack or stroke.**
- **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.**

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 room temperature between 68°F to 77°F (20°C to 25°C).
- 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.

You can ask your pharmacist or healthcare provider for information about FORTESTA that is written for health professionals.

What are the ingredients in FORTESTA?

Active ingredients: testosterone

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

Manufactured by:

Pharbil Waltrop GmbH
Im Wirrigen 25, 45731
Waltrop, Germany

Distributed by:

Endo Pharmaceuticals Inc.
Malvern, PA 19355

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

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

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