MEDICATION GUIDE

Testosterone (tes-TOS-te-rōn) Gel, CIII

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

What is the most important information I should know about testosterone gel?

1. **Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using testosterone gel.**

   Signs and symptoms of early puberty in a child may include:

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

   Testosterone gel can transfer from your body to others.

2. **Women and children should avoid contact with the unwashed or unclothed area where testosterone gel has been applied to your skin.**

   Stop using 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 testosterone gel.

   Signs and symptoms of exposure to testosterone gel in children may include:

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

   Signs and symptoms of exposure to testosterone gel in women may include:

   - changes in body hair
   - a large increase in acne

   To lower the risk of transfer of testosterone gel from your body to others, you should follow these important instructions:

   - Apply testosterone gel **only** to the areas of your shoulders and upper arms that will be covered by a short sleeve T-shirt.
   - Wash your hands **right away** with soap and water after applying testosterone gel.
   - 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 woman or child makes contact with the testosterone gel application area, that area on the woman or child should be washed well with soap and water right away.**

What is testosterone gel?

Testosterone gel is a prescription medicine that contains testosterone. Testosterone gel 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 taking testosterone gel.

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

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

Testosterone gel is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your testosterone gel in a safe place to protect it. Never give your testosterone gel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and it is against the law.

Testosterone gel is not meant for use in women.

Who should not use testosterone gel?

Do not use testosterone gel if you:

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

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

What should I tell my healthcare provider before using testosterone gel?

Before you use testosterone gel, 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 over-the-counter medicines, vitamins, and herbal supplements.
Testosterone gel and certain other medicines you take 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 testosterone gel?

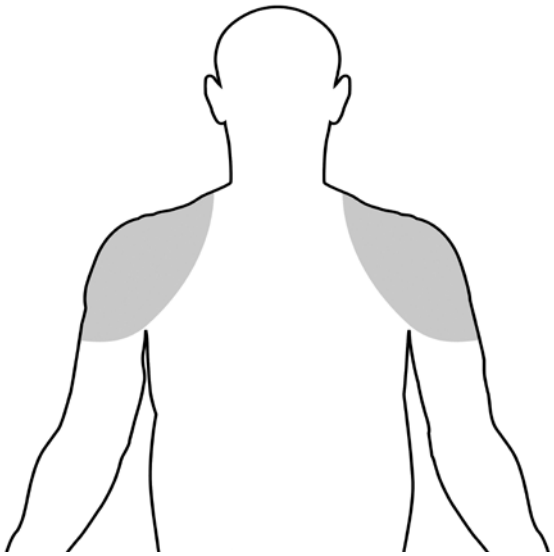
- It is important that you apply testosterone gel exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much testosterone gel to apply and when to apply it.
- Your healthcare provider may change your testosterone gel dose. **Do not** change your testosterone gel dose without talking to your healthcare provider.
- **Testosterone gel is to be applied only to the areas of your shoulders and upper arms that will be covered by a short sleeve t-shirt. Do not** apply testosterone gel to any other parts of your body such as your penis, scrotum, or stomach area (abdomen).
- Apply testosterone gel at the same time each day. Testosterone gel should be applied after showering or bathing.
- **Wash your hands right away with soap and water** after applying testosterone gel.
- Avoid showering, swimming, or bathing for at least 2 hours after you apply testosterone gel.
- Testosterone gel is flammable until dry. Let testosterone gel dry before smoking or going near an open flame.
- Let the application areas dry before putting on a t-shirt.

Applying testosterone gel:

Testosterone gel comes in tubes, packets, or in a pump.

- **Before applying testosterone gel, make sure that your shoulders and upper arms are clean, dry, and there is no broken skin.**
- The application sites for testosterone gel are the shoulders and the upper arms that will be covered by a short sleeve t-shirt (See Figure A).

Figure A



If you are using testosterone gel tubes:

- Remove the cap from the tube and use the top of the cap to puncture the metal seal on the top of the tube.
- Squeeze from the bottom of the tube to the top.
- Squeeze all of the testosterone gel out of the tube into the palm of your hand.
- Apply testosterone gel to the application site. Rub the gel onto your skin for several seconds. Let the application site dry for a few minutes before putting on a T-shirt.
- **Wash your hands with soap and water right away.**
- Put the cap back on the tube.

If you are using testosterone gel packets:

- Tear open the packet completely at the notch on the top edge. Squeeze from the bottom of the packet to the top.
- Squeeze all of the testosterone gel out of the packet into the palm of your hand. Apply testosterone gel to the application site. Rub the gel onto your skin for several seconds. Let the application site dry for a few minutes before putting on a T-shirt.
- **Wash your hands with soap and water right away.**

If you are using the testosterone gel pump:

- Before using a new bottle of testosterone gel for the **first time**, you will need to prime the pump. To prime the testosterone gel pump, remove the cap and slowly push the pump all the way down 3 times.
- **Do not** use any testosterone gel that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your testosterone gel pump is now ready to use.

- Remove the cap from the pump. Then position the nozzle over the palm of your hand and slowly push the pump all the way down. Your healthcare provider will tell you the number of times to press the pump for each dose.
- Apply testosterone gel to the application site. Rub the gel onto your skin for several seconds. Let the application site dry for a few minutes before putting on a T-shirt.
- **Wash your hands with soap and water right away.**
- Put the cap back on the pump.

What are the possible side effects of testosterone gel?

Testosterone gel can cause serious side effects including:

- See **"What is the most important information I should know about testosterone gel?"**
- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using testosterone gel.** 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 testosterone gel.
- **Blood clots in your legs or lungs.** Signs and symptoms of a blood clot in your legs 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 testosterone gel may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Having problems breathing while you sleep (sleep apnea).**

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

The most common side effects of testosterone gel include:

- skin irritation where testosterone gel is applied
- increased red blood cell count
- headache

- increased blood pressure

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 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.

How should I store testosterone gel?

- Store testosterone gel between 68ºF to 77ºF (20ºC to 25ºC).
- Safely throw away used testosterone gel containers in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep testosterone gel away from fire.

Keep testosterone gel and all medicines out of the reach of children.

General information about the safe and effective use of testosterone gel.

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

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

For more information, go to www.upsher-smith.com or call 1-888-650-3789.

What are the ingredients in testosterone gel?

Active ingredient: testosterone

Inactive ingredients: carbomer copolymer Type B, carbomer homopolymer Type C, diisopropyl adipate, ethyl alcohol, glycerin, methyl laurate, oleyl alcohol, polyethylene glycol, propylene glycol, purified water, and tromethamine

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

Manufactured for
USL PHARMA, INC.
Denver, CO 80223
MADE IN CANADA
Revised 0515