

Medication Guide
Testim® (TĚS tim) CIII
(testosterone gel)

Read this Medication Guide that comes with Testim 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 Testim?

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

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

Testim can transfer from your body to others.

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

Stop using Testim 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 Testim.

Signs and symptoms of exposure to Testim 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 Testim in women may include:

- changes in body hair
- a large increase in acne

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

- Apply Testim **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 Testim.
- 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 Testim application area, that area on the woman or child should be washed well with soap and water right away.**

What is Testim?

Testim is a prescription medicine that contains testosterone. Testim 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 use Testim.

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

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

Testim is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your Testim in a safe place to protect it. Never give your Testim 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.

Testim is not meant for use in women.

Who should not use Testim?

Do not use Testim if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or are breastfeeding. Testim 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 Testim 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 Testim?

Before you use Testim, 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 Testim 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 Testim?

- It is important that you apply Testim exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much Testim to apply and when to apply it.
- Your healthcare provider may change your Testim dose. **Do not** change your Testim dose without talking to your healthcare provider.
- **Testim is to be applied to the areas of your shoulders and upper arms that will be covered by a short sleeve T-shirt. Do not** apply Testim to any other parts of your body such as your stomach area (abdomen), penis, or scrotum.
- Apply Testim at the same time each morning. Testim should be applied after showering or bathing.
- **Wash your hands with soap and water right away** after applying Testim.
- Avoid showering, swimming, or bathing for at least 2 hours after you apply Testim.

- Testim is flammable until dry. Let the Testim dry before smoking or going near an open flame.
- Let the application areas dry for a few minutes before putting on a T-shirt.

Applying Testim:

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

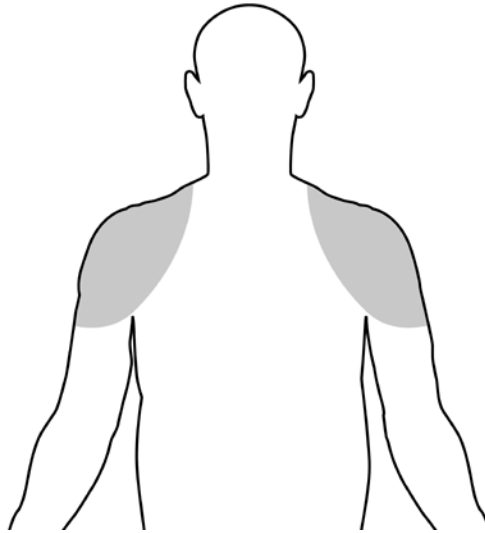


Figure A

- Remove the cap from the tube and use the top of the cap to pierce the metal seal on the top of the tube by pushing or screwing the cap in.
- Squeeze all of the Testim out of the tube into the palm of your hand. Squeeze from the bottom of the tube to the top.
- Apply all of the Testim to the application sites. 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** after applying Testim.

What are the possible side effects of Testim?

Testim can cause serious side effects including:

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

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using Testim.** 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 Testim.
- **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 Testim 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.**
- **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 Testim include:

- skin irritation where Testim 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 Testim. For more information, ask your healthcare provider or pharmacist.

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

How should I store Testim?

- Store Testim between 59°F to 86°F (15°C to 30°C).
- Safely throw away used Testim in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep Testim away from fire.

Keep Testim and all medicines out of the reach of children.**General information about the safe and effective use of Testim.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Testim for a condition for which it was not prescribed. Do not give Testim 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 Testim. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Testim that is written for health professionals.

For more information, go to www.TESTIM.com or call 1-877-663-0412.

What are the ingredients in Testim?

Active ingredient: testosterone

Inactive ingredients: purified water, pentadecalactone, carbopol, acrylates, propylene glycol, glycerin, polyethylene glycol, ethanol (74%), and tromethamine.

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

Manufactured for:
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San Antonio, TX 78215

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