

Medication Guide
Testim[®] (TĚS tim)
(testosterone gel) for topical use, CIII

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

1. **Testim 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 Testim 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 Testim.

Children

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

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

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 happened through accidental touching of the area where you have placed Testim.

2. **To lower the risk of transfer of Testim from your body to others, 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 child or woman touches the area where you have applied Testim, that area on the child or woman 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 are using 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.

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.

Before using Testim, 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 Testim 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 Testim?

- See the detailed **Instructions for Use** for information about how to use Testim at the end of this Medication Guide.
- It is important that you apply Testim exactly as your healthcare provider tells you to.
- Your healthcare provider may change your Testim dose. **Do not** change your Testim dose without talking to your healthcare provider.
- Apply Testim at the same time each morning. Testim should be applied after showering or bathing.

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 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 doctor 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.

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

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.

Distributed by:

Endo Pharmaceuticals Inc. Malvern, PA 19355

Manufactured by:

DPT Laboratories, Ltd. San Antonio, TX 78215

or

Contract Pharmaceuticals Limited Mississauga, ON, Canada L5N 6R8

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

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 05/2019

INSTRUCTIONS FOR USE

Testim[®] (TĚS tim)
(testosterone gel)
for topical use, CIII

Read this Instructions for Use for Testim before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

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). **Do not** apply Testim to any other parts of your body such as your stomach area (abdomen), penis, or scrotum.

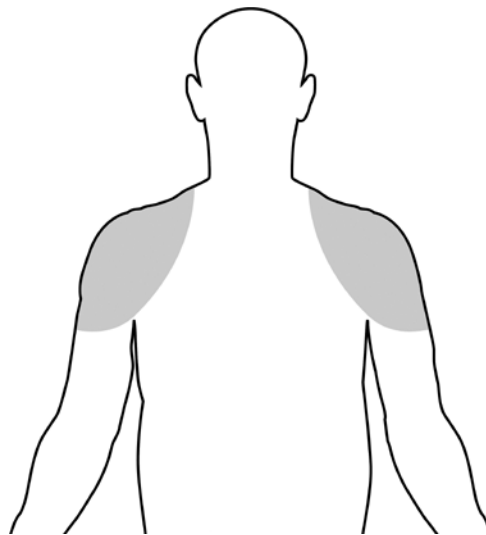


Figure A

- 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 by pushing or screwing the cap in.
- Apply all of the Testim 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.**
- **Testim is flammable until dry. Let the Testim dry before smoking or going near an open flame.**

- **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.

How should I store Testim?

- Store Testim at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away used Testim in the 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.

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