

MEDICATION GUIDE

CIII

Testosterone (tes-TOS-te-rōn) Gel

Read the Medication Guide that comes with testosterone gel before you start taking 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 areas that will be covered by a short sleeve t-shirt. These areas are your shoulders and upper arms, or stomach area (abdomen), or shoulders, upper arms and stomach area.
- 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.

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 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 breast-feeding. Testosterone gel 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 testosterone gel has been applied.

- are allergic to testosterone or any of the ingredients in testosterone gel including soy. See the end of this Medication Guide for a complete list of ingredients in testosterone gel.

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 testosterone gel?

Before you use testosterone gel, tell your healthcare provider if you:

- have breast cancer or 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 testosterone gel with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:

- insulin
- corticosteroids
- medicines that decrease blood clotting

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

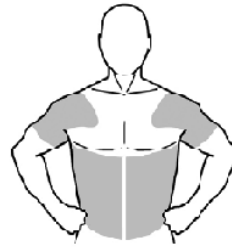
How should I use testosterone gel?

- It is important that you apply testosterone gel exactly as prescribed by your healthcare provider. 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 for skin use only.
- **Do not allow others to apply testosterone gel to your body.**

Applying testosterone gel:

- Tear open the packet completely at the dotted line.
- Squeeze all of the testosterone gel out of the packet into the palm of your hand. Squeeze from the bottom of the packet to the top.

- Throw away the packet in the trash out of the reach of children to avoid accidental exposure.
- Squeeze the medicine into the palm of your hand and apply to clean, dry, intact skin at the same time each day.
- You may also apply testosterone gel from the packet directly to your skin.
- **Apply testosterone gel only to areas that will be covered by a short sleeve t-shirt, as shown in the shaded areas in the figure below. These areas are your shoulders and upper arms, or stomach area, or shoulders, upper arm and stomach area.**



- **Do not apply testosterone gel to your penis or scrotum.**
- **Wash your hands with soap and water right after you apply testosterone gel.**
- Let the application areas dry for a few minutes before putting on a shirt.
- To prevent transfer of testosterone gel to others, clothes (such as a t-shirt) should **always** be worn to cover the testosterone gel application areas until you have washed the application areas well with soap and water.
- **Wait 5 hours before showering or swimming. This will ensure that the greatest amount of testosterone gel is absorbed into your system.**
- **Testosterone gel is flammable until dry. Let the gel dry before smoking or going near an open flame.**

Your healthcare provider will test your blood before you start and while you take testosterone gel.

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.
 - **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).**
 - **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 testosterone gel include:

- acne
- skin irritation where testosterone gel is applied
- increased cholesterol levels
- increased prostate specific antigen (a test used to screen for prostate cancer)
- increased red blood cell count
- increased liver function tests

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 at 20°C to 25°C (68°F to 77°F)
- Safely throw away used testosterone gel 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 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 you have. It may harm them.

This Medication Guide summarizes the most important information about testosterone gel. If you would like more information, talk to 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, call 1-888-838-2872.

What are the ingredients in testosterone gel?

Active ingredient: testosterone

Inactive ingredients: carbomer homopolymer type C, dehydrated alcohol 67%, isopropyl palmitate, purified water, and sodium hydroxide.

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

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