

MEDICATION GUIDE
Testosterone Gel 1.62%, for topical use, CIII
(tes TOS ter one)

What is the most important information I should know about testosterone gel 1.62%?

- 1. Testosterone gel 1.62% 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 testosterone gel 1.62% 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 testosterone gel 1.62%.

Children

Signs and symptoms of early puberty in a child when they come in direct contact with testosterone gel 1.62% 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 testosterone gel 1.62% may include:

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

Stop using testosterone gel 1.62% 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 testosterone gel 1.62%.

2. To lower the risk of transfer of testosterone gel 1.62% from your body to others, follow these important instructions:

- Apply testosterone gel 1.62% only to 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 1.62%.
- 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 testosterone gel 1.62%, that area on the child or woman should be washed well with soap and water right away.

What is testosterone gel 1.62%?

Testosterone gel 1.62% is a prescription medicine that contains testosterone. Testosterone gel 1.62% 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 testosterone gel 1.62%.
- It is not known if testosterone gel 1.62% is safe or effective to treat men who have low testosterone due to aging.
- It is not known if testosterone gel 1.62% is safe or effective in children younger than 18 years old. Improper use of testosterone gel 1.62% may affect bone growth in children.

Testosterone gel 1.62% is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your testosterone gel 1.62% in a safe place to protect it. Never give your testosterone gel 1.62% 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 1.62% is not meant for use in women.

Do not use testosterone gel 1.62% if you:

- have breast cancer.
- have or might have prostate cancer.
- are pregnant. Testosterone gel 1.62% may harm your unborn baby.
- Women who are pregnant should avoid contact with the area of skin where testosterone gel 1.62% has been applied.

Before using testosterone gel 1.62%, 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 kidney or liver 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 testosterone gel 1.62% 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 testosterone gel 1.62%?

- See the detailed **Instructions for Use** about how to use testosterone gel 1.62% at the end of this Medication Guide.
- It is important that you apply testosterone gel 1.62% exactly as your healthcare provider tells you to.
- Your healthcare provider may change your testosterone gel 1.62% dose. **Do not** change your testosterone gel 1.62% dose without talking to your healthcare provider.
- Apply testosterone gel 1.62% at the same time each morning. Testosterone gel 1.62% should be applied after showering or bathing.

What are the possible side effects of testosterone gel 1.62%?

Testosterone gel 1.62% can cause serious side effects including:

See “**What is the most important information I should know about testosterone gel 1.62%?**”

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using testosterone gel 1.62%.** 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 testosterone gel 1.62%.
- **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 testosterone gel 1.62% 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).**

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 1.62% include:

- increased prostate specific antigen (a test used to screen for prostate cancer)
- mood swings
- hypertension
- increased red blood cell count
- skin irritation where testosterone gel 1.62% is applied

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 1.62%. 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.

General information about the safe and effective use of testosterone gel 1.62%

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use testosterone gel 1.62% for a condition for which it was not prescribed. Do not give testosterone gel 1.62% 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 testosterone gel 1.62% that is written for health professionals.

What are the ingredients in testosterone gel 1.62%?

Active ingredient: testosterone USP

Inactive ingredients: carbomer homopolymer type C, dehydrated alcohol (68.1%w/w), isopropyl myristate, sodium hydroxide and purified water.

For more information, call 1-800-399-2561.

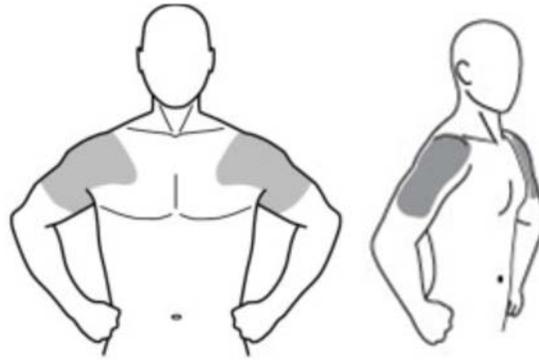
This Medication Guide has been approved by the U.S. Food and Drug Administration.

INSTRUCTIONS FOR USE
Testosterone Gel 1.62%, for topical use, CIII
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Read this Instructions for Use for testosterone gel 1.62% 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 testosterone gel 1.62%:

- **Testosterone gel 1.62% comes in a pump.**
- **Before applying testosterone gel 1.62% make sure that your shoulders and upper arms are clean, dry, and that there is no broken skin.**
- **Testosterone gel 1.62% is to be applied to the area of your shoulders and upper arms that will be covered by a short sleeve t-shirt (See Figure A). Do not apply testosterone gel 1.62% to any other parts of your body such as your stomach area (abdomen), penis, scrotum, chest, armpits (axillae), or knees.**



(Figure A)

If you are using testosterone gel 1.62% pump:

- Before using a new bottle of testosterone gel 1.62 % for the first time, you will need to remove the cap and then prime the pump. To prime the testosterone gel 1.62% pump, slowly push the pump all the way down 3 times, over the sink drain. **Do not** use any testosterone gel 1.62% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your testosterone gel 1.62% pump is now ready to use.
- Remove the cap from the pump. Then, put the spout opening at the top of the pump where the medicine comes out over the palm of your hand and slowly push the pump all the way down. Apply testosterone gel 1.62% to the application site. You may also apply testosterone gel 1.62% directly to the application site. **Your healthcare provider will tell you the number of times to press the pump for each dose.**
- **Wash your hands with soap and water right away.**

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|---|---------------------------|
| Find Your Dose as Prescribed by Your Healthcare Provider | Application Method |
|---|---------------------------|

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|---------|----------|--|
| 1 pump | 20.25 mg | Apply 1 pump of testosterone gel 1.62% to 1 upper arm and shoulder. |
| 2 pumps | 40.5 mg | Apply 1 pump of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 1 pump of testosterone gel 1.62% to the opposite upper arm and shoulder. |
| 3 pumps | 60.75 mg | Apply 2 pumps of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 1 pump of testosterone gel 1.62% to the opposite upper arm and shoulder. |
| 4 pumps | 81 mg | Apply 2 pumps of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 2 pumps of testosterone gel 1.62% to the opposite upper arm and shoulder. |

How should I store testosterone gel 1.62%?

- Store testosterone gel 1.62% at room temperature between 68°F to 77°F (20°C to 25°C).
- When it is time to throw away the pump, safely throw away used testosterone gel 1.62% in the household trash. Be careful to prevent accidental exposure of children or pets.
- Keep testosterone gel 1.62% away from fire.

Keep testosterone gel 1.62% and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:

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Baltimore, Maryland 21202
United States

Manufactured by:

Lupin Limited
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