

MEDICATION GUIDE

Testosterone (tes TOS ter one) Topical Solution USP, for topical use, CIII

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

- 1. Testosterone topical solution 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 topical solution 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 topical solution.

Children

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

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

Stop using testosterone topical solution 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 topical solution:

- 2. To lower the risk of transfer of testosterone topical solution from your body to others, follow these important instructions:**

- Apply testosterone topical solution only to your armpits.
- Wash your hands right away with soap and water after applying testosterone topical solution.
- After the solution 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 topical solution, that area on the child or woman should be washed well with soap and water right away.

What is testosterone topical solution?

- Testosterone topical solution is a prescription medicine that contains testosterone. Testosterone topical solution 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 topical solution.
 - It is not known if testosterone topical solution is safe or effective to treat men who have low testosterone due to aging.

- It is not known if testosterone topical solution is safe and effective in children younger than 18 years old. Improper use of testosterone topical solution may affect bone growth in children.
- Testosterone topical solution is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your testosterone topical solution in a safe place to protect it. Never give testosterone topical solution 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 topical solution is not meant for use in women.

Do not use testosterone topical solution if you:

- have breast cancer.
- have or might have prostate cancer.
- are pregnant or may become pregnant or are breastfeeding. Testosterone topical solution may harm your unborn or breastfeeding baby.

Women who are pregnant or who may become pregnant should avoid contact with the area of the skin where testosterone topical solution has been applied.

Before using testosterone topical solution, 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 of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using testosterone topical solution with 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 topical solution?

- See the detailed **Instructions for Use** for information about how to use testosterone topical solution at the end of this Medication Guide.
- **Testosterone topical solution comes in a metered-dose pump or twist actuated dispenser. Make sure you have the right pump or dispenser that is prescribed for you.**
- It is important that you apply testosterone topical solution exactly as your healthcare provider tells you to.
- Your healthcare provider may change your testosterone topical solution dose. **Do not** change your testosterone topical solution dose without talking to your healthcare provider.
- Apply testosterone topical solution at about the same time each morning. Testosterone topical solution should be applied after showering or bathing.

What are the possible side effects of testosterone topical solution?

Testosterone topical solution can cause serious side effects including:

See also “**What is the most important information I should know about testosterone topical solution?**”

- **If you already have an enlarged prostate, your symptoms can get worse while using testosterone topical solution.** 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 topical solution.
- **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 topical solution 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 topical solution include:

- skin redness or irritation where testosterone topical solution is applied
- increased red blood cell count
- headache
- diarrhea
- vomiting
- increase in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer)

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 topical solution. 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 topical solution.

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

What are the ingredients in testosterone USP topical solution?

Active ingredient: testosterone USP.

Inactive ingredients: ethanol, isopropyl alcohol, octisalate, and povidone.

The bottle and the applicator cup are not made with natural rubber latex.

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

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

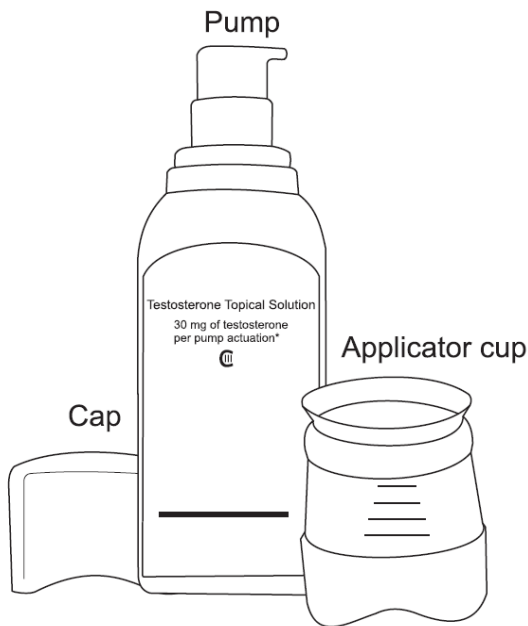
INSTRUCTIONS FOR USE

Testosterone (tes TOS ter one) Topical Solution USP, for topical use, CIII

Read this Instructions for Use for testosterone topical solution 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 Topical Solution:

- **Testosterone topical solution is to be applied to the armpits only.** Do not apply testosterone topical solution to any other parts of your body such as your stomach area (abdomen), penis, scrotum, shoulders or upper arms.
- Do not apply testosterone topical solution with your fingers or hands.
- Apply testosterone topical solution at about the same time each morning. Testosterone topical solution should be applied after showering or bathing.
- Avoid swimming or bathing for at least 2 hours after you apply testosterone topical solution.
- You can use an antiperspirant or deodorant before applying testosterone topical solution. If you use antiperspirant or deodorant, then it should be applied at least 2 minutes before you apply testosterone topical solution.
- **Testosterone topical solution is flammable until dry. Let testosterone topical solution dry before smoking or going near an open flame.**
- **Avoid splashing in the eyes. In case of contact with eyes, flush thoroughly with water. If irritation persists, seek medical advice.**



- Before using a new bottle of testosterone topical solution for the first time, you will need to prime the pump. To prime the testosterone topical solution pump gently push down on the pump 3 times. Do not use any testosterone topical solution that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your testosterone topical solution pump is now ready to use.
- **Use testosterone topical solution exactly as your healthcare provider tells you to use it.** Your healthcare provider will tell you the dose of testosterone topical solution that is right for you. Apply your dose correctly by following the application instructions in the table below.

**Testosterone Topical Solution
Figure 1**

Find Your Dose as Prescribed by Your Healthcare Provider	Each application equals 1 press (depression) of the pump.
30 mg	Apply 1 application one time to one armpit only (left or right).
60 mg	Apply 2 applications: one to the left armpit and then one to the right armpit.
90 mg	Apply 3 applications: one to the left and one to the right armpit, wait for the product to dry, and then apply again one to the left or right armpit.
120 mg	Apply 4 applications: one to the left and one to the right armpit, wait for the product to dry, and then apply again one to the left and one to the right armpit.

- Before applying testosterone topical solution, make sure that your armpit is clean, dry and that there is no broken skin.



Figure 2

- Remove the cap and the applicator cup from the pump. Then, position the nozzle over the applicator cup and gently press down on (depress) the pump (*see Figure 2*).



Figure 3

- To apply the testosterone topical solution, keep the applicator upright, place it up into the armpit application site and wipe steadily down and up (*see Figure 3*).
- If testosterone topical solution drips or runs, wipe it back up with the applicator cup. Do not rub in the solution with your fingers or hand once it has been applied.

- Let the application site dry completely for 3 minutes before putting on a shirt.

- After you have finished applying testosterone topical solution, rinse the applicator cup with room temperature running water, and then pat it dry with a tissue. Carefully replace the applicator cup and cap back onto the bottle and make sure you store the bottle safely.
- Clean up any spilled solution from surfaces such as the sink or floor to make sure others do not come into contact with it.
- **Wash your hands with soap and water right away.**

How should I store testosterone topical solution?

- Store testosterone topical solution upright at room temperature between 68°F to 77°F (20°C to 25°C).
- When it is time to throw away the bottle, safely throw away all parts of the testosterone topical solution dispenser including the bottle applicator cup and cap into the household trash.
- Be careful to prevent accidental exposure of children or pets.
- Keep testosterone topical solution away from fire.

Keep testosterone topical solution 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:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) – 454 775

India

April 2020

ID#: 262879

Market/Customer :	Lupin	Location :	Pithampur
Prepared On :	03/03/2020	Version No. :	02
Product Name :	MG TESTOSTERONE TOP SOLN USP US R2	Supersedes Material code :	259999
Material Code :	262879	Barcode value :	NA
Open Size :	NA	Barcode Type (Ex. NDC, PZN, EAN-13)	NA
Folded Size :	NA	Component :	MEDGUIDE
Substrate :	NA	Font Size :	NA
Font Name :	NA	Gluing :	NA
Perforation :	NA	No. of pages or Leafs/PAD	NA
Cover Page Substrate :	NA	No. of pages or Leafs/PAD	NA
Pantone Colours :	NA		
Reason for Change :	Product name updated.		