

Initial REMS Approval: 11/2015

## **RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

ANDA 76737

Testosterone Gel 1%

Class of Drug: Androgen

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### **I. Goal**

The goal of this REMS is to inform patients about the serious risks associated with the use of Testosterone Gel 1%.

### **II. REMS Elements A.**

#### **Medication Guide**

A Medication Guide will be dispensed with each Testosterone Gel 1% prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

**MEDICATION GUIDE**  
**Testosterone (tes-TOS-ter-one) Gel 1% CIII**

Read this Medication Guide that comes with testosterone gel 1% 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%?**

- 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 1%.**

**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 1% can transfer from your body to others.**

- 2. Women and children should avoid contact with the unwashed or unclothed area where testosterone gel 1% has been applied to your skin.**

**Stop using testosterone gel 1% 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 1%.**

**Signs and symptoms of exposure to testosterone gel 1% 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 1% in women may include:**

- changes in body hair
- a large increase in acne
- **To lower the risk of transfer of testosterone gel 1% from your body to others, you should follow these important instructions:**
  - Apply testosterone gel 1% **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 1%.
  - 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 1% application area, that area on the woman or child should be washed well with soap and water right away.**

### **What is testosterone gel 1%?**

Testosterone gel 1% is a prescription medicine that contains testosterone. Testosterone gel 1% 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 taking testosterone gel 1%.

It is not known if testosterone gel 1% is safe or effective to treat men who have low testosterone due to aging.

It is not known if testosterone gel 1% is safe or effective in children younger than 18 years old. Improper use of testosterone gel 1% may affect bone growth in children.

Testosterone gel 1% 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% in a safe place to protect it. Never give your testosterone gel 1% 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% is not meant for use in women.

### **Who should not use testosterone gel 1%?**

#### **Do not use testosterone gel 1% if you:**

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or breastfeeding. Testosterone gel 1% 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 testosterone gel 1% 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 testosterone gel 1%?**

#### **Before you use testosterone gel 1%, 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 testosterone gel 1% with certain other medicines can affect each other. Especially, tell your healthcare provider if you take:

- insulin
- corticosteroids
- medicines that decrease blood clotting

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.

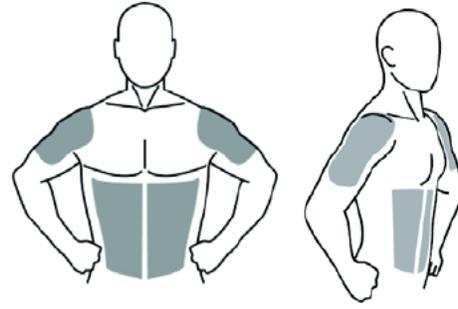
### **How should I use testosterone gel 1%?**

- It is important that you apply testosterone gel 1% exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much testosterone gel 1% to apply and when to apply it.
- Your healthcare provider may change your testosterone gel 1% dose. **Do not** change your testosterone gel 1% dose without talking to your healthcare provider.
- **Testosterone gel 1% is to be applied to the area of your shoulders, upper arms, or abdomen that will be covered by a short sleeve t-shirt. Do not** apply testosterone gel 1% to any other parts of your body such as your penis, scrotum, chest, armpits (axillae), knees, or back.
- Apply testosterone gel 1% at the same time each morning. Testosterone gel 1% should be applied after showering or bathing.
- **Wash your hands right away** with soap and water after applying testosterone gel 1%.
- Avoid showering, swimming, or bathing for at least 5 hours after you apply testosterone gel 1%.
- Testosterone gel 1% is flammable until dry. Let testosterone gel 1% dry before smoking or going near an open flame.
- Let the application areas dry completely before putting on a t-shirt.

### **Applying testosterone gel 1%:**

**Testosterone gel 1% comes in a pump or in packets.**

- **Before applying testosterone gel 1%, make sure that your shoulders, upper arms, and abdomen are clean, dry, and there is no broken skin.**
- The application sites for testosterone gel 1% are the shoulders, upper arms, or abdomen that will be covered by a short sleeve t-shirt (See Figure A).



(Figure A)

**If you are using the testosterone gel 1% pump:**

- Before using a new bottle of testosterone gel 1% for the first time, you will need to prime the pump. To prime the testosterone gel 1% pump, slowly push the pump all the way down 3 times. **Do not** use any testosterone gel 1% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your testosterone gel 1% pump is ready to use.
- Remove the cap from the pump. Then, position the nozzle over the palm of your hand and slowly push the pump all the way down. Apply testosterone gel 1% to the application site. You may also apply testosterone gel 1% directly to the application site.
- **Wash your hands with soap and water right away.**
- Your healthcare provider will tell you the number of times to press the pump for each dose.

**If you are using testosterone gel 1% packets:**

- Locate a tear notch on either corner at the top of your testosterone gel 1% packet. Fold the packet corner to expose the tear notch, and tear open the packet using the tear notch. Squeeze from the bottom of the packet to the top.
- Squeeze all of the testosterone gel 1% out of the packet into the palm of your hand. Apply testosterone gel 1% to the application site. You may also apply testosterone gel 1% from the packet directly to the application site.
- Testosterone gel 1% should be applied right away.
- **Wash your hands with soap and water right away.**

**What are the possible side effects of testosterone gel 1%?**

See “What is the most important information I should know about testosterone gel 1%?”

**Testosterone gel 1% can cause serious side effects including:**

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using testosterone gel 1%.** 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 1%.
- **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% 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% include:**

- acne
- skin irritation where testosterone gel 1% is applied
- lab test changes
- increased 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 gel 1%. 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 1%?**

- Store testosterone gel 1% between 68° to 77°F (20° to 25°C).
- Safely throw away used testosterone gel 1% in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep testosterone gel 1% away from fire.

**Keep testosterone gel 1% and all medicines out of the reach of children.**

**General information about the safe and effective use of testosterone gel 1%**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use testosterone gel 1% for a condition for which it was not prescribed. Do not give

testosterone gel 1% 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 1%. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about testosterone gel 1% that is written for health professionals.

For more information, go to [www.actavis.com](http://www.actavis.com) or call Actavis at 1-800-272-5525.

**What are the ingredients in testosterone gel 1%?**

**Active ingredient:** testosterone

**Inactive ingredients:** carbomer homopolymer type C, ethyl alcohol 68.9%, isopropyl myristate, purified water, and sodium hydroxide.

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

Manufactured by:

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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TRUEMAN W SHARP  
11/05/2015