

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22309Orig1s000

REMS

Initial REMS Approval: 04/2011

NDA 22-309 AndroGel® (testosterone gel) 1.62% CIII

Drug Class and Formulation: Testosterone Gel Products

**Abbott Products, Inc.
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

To inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1.62%.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each AndroGel (testosterone gel) 1.62% prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Abbott Products Inc. will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

Abbott Products Inc. will submit each assessment so that it will be received by the FDA on or before the due date.

Medication Guide
ANDROGEL® (ANDROGEL) CIII
(testosterone gel) 1.62%

Read this Medication Guide before you start using ANDROGEL 1.62% and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

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

ANDROGEL 1.62% can transfer from your body to others. This can happen if other people come into contact with the area where the ANDROGEL 1.62% was applied.

Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through skin-to-skin contact with men using topical testosterone products like ANDROGEL 1.62%.

- **Women and children should avoid contact with the unwashed or unclothed area where ANDROGEL 1.62% has been applied. If a woman or child makes contact with the ANDROGEL 1.62% application area, the contact area on the woman or child should be washed well with soap and water right away.**
- To lower the risk of transfer of ANDROGEL 1.62% from your body to others, you should follow these important instructions:
 - Apply ANDROGEL 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 ANDROGEL 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 another person to have skin-to-skin contact with your shoulders or upper arms, first wash the application area well with soap and water.**

Stop using ANDROGEL 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 occurred through accidental exposure to ANDROGEL 1.62%.

Signs and symptoms in **children** may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms in **women** may include:

- changes in body hair
- a large increase in acne

What is ANDROGEL 1.62%?

ANDROGEL 1.62% is a prescription medicine that contains testosterone. ANDROGEL 1.62% is used to treat adult males who have low or no testosterone.

Your healthcare provider will test your blood before you start and while you are taking ANDROGEL 1.62%.

It is not known if ANDROGEL 1.62% is safe or effective in children younger than 18 years old. Improper use of ANDROGEL 1.62% may affect bone growth in children.

ANDROGEL 1.62% is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your ANDROGEL 1.62% in a safe place to protect it. Never give your ANDROGEL 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.

ANDROGEL 1.62% is not meant for use in women.

Who should not use ANDROGEL 1.62%?

Do not use ANDROGEL 1.62% if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or are breast-feeding.
ANDROGEL 1.62% 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 ANDROGEL 1.62% 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 ANDROGEL 1.62%?

Before you use ANDROGEL 1.62%, 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 kidney or liver 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 ANDROGEL 1.62% with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting
- corticosteroids

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of all of your 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.

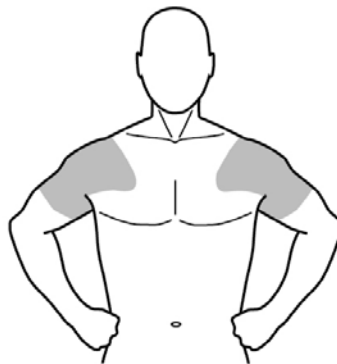
How should I use ANDROGEL 1.62%?

- It is important that you apply ANDROGEL 1.62% exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much ANDROGEL 1.62% to apply and when to apply it.
- Your healthcare provider may change your ANDROGEL 1.62% dose. Do not change your ANDROGEL 1.62% dose without talking to your healthcare provider.
- **ANDROGEL 1.62% is to be applied to the area of shoulders and upper arms that will be covered by a short sleeve t-shirt.** Do not apply ANDROGEL 1.62% to any other parts of your body such as your stomach area (abdomen), penis, or scrotum.
- Apply ANDROGEL 1.62% at the same time each morning. ANDROGEL 1.62% should be applied after showering or bathing.

- Wash your hands **right away** with soap and water after applying ANDROGEL 1.62%.
- Avoid showering, swimming or bathing for at least 2 hours after you apply ANDROGEL 1.62%.
- ANDROGEL 1.62% is flammable until dry. Let ANDROGEL 1.62% dry before smoking or going near an open flame.

Applying ANDROGEL 1.62%:

- Before using a new bottle of ANDROGEL 1.62 % for the first time, you will need to prime the pump. To prime the ANDROGEL 1.62% pump, slowly push the pump all the way down 3 times. Do not use any ANDROGEL 1.62% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your ANDROGEL 1.62% pump is now ready to use.
- **Use ANDROGEL 1.62% exactly as your healthcare provider tells you to use it.** Your healthcare provider will tell you the dose of ANDROGEL 1.62% that is right for you.
- **Before applying ANDROGEL 1.62% make sure that your shoulders and upper arms are clean, dry, and that there is no broken skin.**
 - Remove the cap from the pump. Then, position the nozzle over the palm of your hand and slowly and fully depress the pump.
 - The application sites for ANDROGEL 1.62% are the upper arms and shoulders that will be covered by a short sleeve t-shirt (See Figure 1).



(Figure 1)

Find Your Dose as Prescribed by Your Physician		Application Method
1 PUMP DEPRESSION	20.25 mg	Using the palm of the hand, apply one depression of ANDROGEL 1.62% to 1 upper arm and shoulder.
2 PUMP DEPRESSIONS	40.5 mg	Using the palm of the hand, apply one pump depression of ANDROGEL 1.62% to one upper arm and shoulder and then apply one pump depression of ANDROGEL 1.62% to the opposite upper arm and shoulder.
3 PUMP DEPRESSIONS	60.75 mg	Using the palm of the hand, apply two pump depressions of ANDROGEL 1.62% to one upper arm and shoulder and then apply one pump depression of ANDROGEL 1.62% to the opposite upper arm and shoulder.
4 PUMP DEPRESSIONS	81 mg	Using the palm of the hand, apply two pump depressions of ANDROGEL 1.62% to one upper arm and shoulder and then apply two pump depressions of ANDROGEL 1.62% to the opposite upper arm and shoulder.

- Let the application site dry completely before putting on a t-shirt.
- **Wash your hands with soap and water right away.**

What are the possible side effects of ANDROGEL 1.62%?

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

ANDROGEL 1.62% can cause serious side effects including:

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

- **In large doses ANDROGEL 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).**
- **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 ANDROGEL 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 ANDROGEL 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 ANDROGEL 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.

How should I store ANDROGEL 1.62%?

- Store ANDROGEL 1.62% at 59°F to 86°F (15°C to 30°C).
- When it is time to throw away the pump, safely throw away used ANDROGEL 1.62% in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep ANDROGEL 1.62% away from fire.

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

General information about the safe and effective use of ANDROGEL 1.62%:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ANDROGEL 1.62% for a condition for which it was not prescribed. Do not give ANDROGEL 1.62% 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 ANDROGEL 1.62%. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ANDROGEL 1.62% that is written for health professionals.

For more information, go to www.androgel.com or call 1-800-241-1643.

What are the ingredients in ANDROGEL 1.62%?

Active ingredient: testosterone

Inactive ingredients: carbopol 980, ethyl alcohol, isopropyl myristate, purified water and sodium hydroxide.

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

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/s/

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