

Keep AndroGel out of the reach of children.

Storage

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Disposal

Used AndroGel pumps or used AndroGel packets should be discarded in household trash in a manner that prevents accidental application or ingestion by children or pets.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (17.3)

17.1 Potential Adverse Reactions with Androgens

Patients should be informed that treatment with androgens may lead to adverse reactions which include:

- Changes in urinary habits such as increased urination at night, trouble starting your urine stream, passing 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 and weak urine flow.
- Breathing disturbances, including those associated with sleep, or excessive daytime sleepiness.
- Too frequent or persistent erections of the penis.
- Nausea, vomiting, changes in skin color, or ankle swelling.

17.2 Instructions for Use of AndroGel

- Patients should be informed to apply AndroGel once daily (preferably in the morning) to clean, dry skin of the shoulders and upper arms and/or abdomen. To prevent transfer of AndroGel to others, patient should wash their hands after application and cover the application site with clothing.
- Advise patients that AndroGel is an alcohol based product and is flammable, therefore avoid fire, flame or smoking until the gel has dried.
- Counsel patients on the importance of adhering to all recommended monitoring by their healthcare professional.
- Advise patients to report any changes in their state of health, such as changes in urinary habits, breathing, sleep, and mood.

17.3 FDA-Approved Patient Labeling

AndroGel (testosterone gel) 1% CIII is available packaged with 2 x 75 g pumps (each pump dispenses 60 metered 1.25 g doses) or in a box of 30 packets with 2.5g or 5g gel.

This is a summary of the important information about AndroGel. For details, talk to your healthcare professional and refer to the package insert.

1. What Disease or Condition Does AndroGel Treat?

Your healthcare provider has prescribed this medication because your body does not produce enough testosterone. The medical term for this condition is hypogonadism.

2. How Should AndroGel (Pump or Packet) Be Applied?

It is important that you use AndroGel as prescribed by your healthcare professional. If you experience serious problems, contact your healthcare professional. Your healthcare professional will tell you how much AndroGel to use each day.

Men should apply gel to starred (upper arm/shoulders) or shaded (abdomen) areas only.

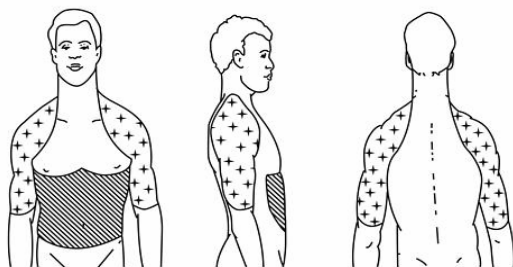


Figure3: Site(s) of Gel Application

- AndroGel should be applied once daily at the same time each day (preferably every morning) to clean, dry, healthy, intact skin of the shoulders, upper arms and/or abdomen. If you take a bath or shower in the morning, use AndroGel **after** your bath or shower.
- AndroGel **should not** be applied to the **penis or scrotum**, or to skin with open sores, wounds or irritation.
- **Wash your hands** with soap and water immediately **after application** to reduce the chance that the medication will spread from your hands to other people.
- Let AndroGel dry for a few minutes before you dress.
- **AndroGel is flammable until dry**; allow the gel to dry before smoking or going near an open flame.
- **Wait 5 to 6 hours** before showering or swimming. This will ensure that the greatest amount of AndroGel is absorbed into your system.

How to use the AndroGel pump?

It is important that you read and follow these directions on how to use the AndroGel Pump properly. Before using the pump for the first time, you must prime the AndroGel pump by fully depressing the pump three times and discarding the gel. The unused gel should be discarded in a manner to avoid accidental exposure or ingestion by household members or pets. Fully depress the pump the appropriate number of times to deliver the daily dose prescribed by your healthcare provider. The product may be delivered directly into the palm of your hand and then applied to the desired application sites, either one pump depression at a time or upon completion of all pump depressions required for the daily dose.

How to use the AndroGel packets?

Open one AndroGel aluminum foil packet by folding the top edge at the perforation and tearing completely across the packet along the perforation. Squeeze the contents into the palm of your hand. Squeeze from the bottom of the packet toward the top. If you like, you may squeeze a portion of the gel from the packet into the palm of your hand and apply to application site(s). Repeat until the entire contents of the packet have been applied.

3. What Should You Discuss With Your Healthcare Professional?

Before you start using AndroGel, tell your healthcare professional if you:

- Have prostate cancer or breast cancer.
- Have a known hypersensitivity to any of AndroGel's components, including individuals who are hypersensitive to testosterone that is chemically synthesized from soy.

4. What Other Drugs Should Not Be Used Together With AndroGel?

Tell your healthcare provider about all of the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. AndroGel can affect how your body handles other drugs. Changes in your dose or careful monitoring may be needed if you are taking any of the following medications:

- Insulin
- Corticosteroids
- Oral Anticoagulants

5. What Are The Side Effects And Risks?

Possible side effects of AndroGel to discuss with your healthcare professional include:

Most common: Skin irritation where gel is applied, breast development or tenderness, acne, prostate enlargement, changes in lab test results and changes in urinary habits.

Contact your healthcare professional if you experience any of the following adverse reactions:

- Too frequent or persistent erections of the penis.
- Any nausea, vomiting, changes in skin color or ankle swelling.
- Breathing disturbances, including those associated with sleep, or excessive daytime sleepiness.
- Changes in urinary habits such as increased urination at night, trouble starting your urine stream, passing 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 and weak urine flow.

The major risks of AndroGel include:

Prostate Disorders: Patients treated with testosterone may be at an increased risk for prostate enlargement, and prostate cancer. Talk to your healthcare provider for more information on risk factors and ways to monitor for prostate disorders.

Testosterone Transfer: Transfer of testosterone to others (including women and children) can occur when vigorous skin-to-skin contact is made with the application site. AndroGel must not be used by women, and exposure to the active ingredient testosterone in pregnancy can cause fetal harm. Notify your healthcare provider if your female partner develops changes in hair distribution, increases in acne or other signs of masculinity.

6. How Should AndroGel Be Stored?

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep out of the reach of children.

7. Is There Anything Else I Need To Know When Using AndroGel?

Your healthcare professional has prescribed AndroGel to meet your specific needs; never share your AndroGel with anyone. If you have any questions or concerns about your AndroGel treatment, ask your healthcare provider or pharmacist.

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