Medication Guide

ANDROGEL® (AN DROW JEL) CIII

(testosterone gel) 1%

Read this Medication Guide that comes with ANDROGEL 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 ANDROGEL 1%?

1. **Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using ANDROGEL 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

ANDROGEL 1% can transfer from your body to others.

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

Stop using ANDROGEL 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 ANDROGEL 1%.

Signs and symptoms of exposure to ANDROGEL 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 ANDROGEL 1% in women may include:

- changes in body hair
- a large increase in acne

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

What is ANDROGEL 1%?

ANDROGEL 1% is a prescription medicine that contains testosterone. ANDROGEL 1% 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%.

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

ANDROGEL 1% is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your ANDROGEL 1% in a safe place to protect it. Never give your ANDROGEL 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.

ANDROGEL 1% is not meant for use in women.

Who should not use ANDROGEL 1%?

Do not use ANDROGEL 1% if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or breast-feeding. ANDROGEL 1% 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% 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%?

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

Applying ANDROGEL 1%:

ANDROGEL 1% comes in a pump or in packets.
- **Before applying ANDROGEL 1%, make sure that your shoulders, upper arms, and abdomen are clean, dry, and there is no broken skin.**
- The application sites for ANDROGEL 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 ANDROGEL 1% pump:

- Before using a new bottle of ANDROGEL 1% for the first time, you will need to prime the pump. To prime the ANDROGEL 1% pump, slowly push the pump all the way down 3 times. **Do not** use any ANDROGEL 1% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your ANDROGEL 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 ANDROGEL 1% to the application site. You may also apply ANDROGEL 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 ANDROGEL 1% packets:

- Tear open the packet completely at the dotted line. Squeeze from the bottom of the packet to the top.
- Squeeze all of the ANDROGEL 1% out of the packet into the palm of your hand. Apply ANDROGEL 1% to the application site. You may also apply ANDROGEL 1% from the packet directly to the application site.
- ANDROGEL 1% should be applied right away.
- **Wash your hands with soap and water right away.**

What are the possible side effects of ANDROGEL 1%?

See **"What is the most important information I should know about ANDROGEL 1%?"**

ANDROGEL 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 ANDROGEL 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 ANDROGEL 1%.
- **In large doses ANDROGEL 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).**
- **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.

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% include:

- acne
- skin irritation where ANDROGEL 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 ANDROGEL 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 ANDROGEL 1%?

- Store ANDROGEL 1% between 59ºF to 86ºF (15ºC to 30ºC).
- Safely throw away used ANDROGEL 1% in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep ANDROGEL 1% away from fire.

Keep ANDROGEL 1% and all medicines out of the reach of children.

General information about the safe and effective use of ANDROGEL 1%

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ANDROGEL 1% for a condition for which it was not prescribed. Do not give ANDROGEL 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 ANDROGEL 1%. If you would like more information, talk to your healthcare provider. You can ask your pharmacist

or healthcare provider for information about ANDROGEL 1% that is written for health professionals.

For more information, go to www.ANDROGEL.com or call 1-800-633-9110.

What are the ingredients in ANDROGEL 1%?

Active ingredient: testosterone

Inactive ingredients: carbomer 980, ethyl alcohol 67.0%, isopropyl myristate, purified water and sodium hydroxide.

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

Marketed by:

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