

MEDICATION GUIDE

ANDROGEL® (AN DROW JEL) CIII
(testosterone gel) 1% for topical use

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

1. **ANDROGEL 1% 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 ANDROGEL® 1% 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 ANDROGEL 1%.

Signs and symptoms of early puberty in a child when they come in direct contact with ANDROGEL 1% 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.

Signs and symptoms in women when they come in direct contact with ANDROGEL 1% may include:

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

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 happened through accidental touching of the area where you have applied ANDROGEL 1%.

2. **To lower the risk of transfer of ANDROGEL 1% from your body to others, follow these important instructions:**

- Apply ANDROGEL 1% only to areas of your shoulders, upper arms, or stomach area (abdomen) that will be covered by a short sleeve T-shirt.
- 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 gel off 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 ANDROGEL 1%, that area on the child or woman 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 due to certain medical conditions.

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

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.

Before using ANDROGEL 1%, 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 liver or kidney problems.
- have problems breathing while you sleep (sleep apnea).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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
- medicines that decrease blood clotting (blood thinners)
- corticosteroids

How should I use ANDROGEL 1%?

- See the detailed **Instructions for Use** for information about how to use ANDROGEL 1% at the end of this Medication Guide.
- It is important that you apply ANDROGEL 1% exactly as your healthcare provider tells you to.
- Your healthcare provider may change your ANDROGEL 1% dose. **Do not** change your ANDROGEL 1% dose without talking to your healthcare provider.
- Apply ANDROGEL 1% at the same time each morning. ANDROGEL 1% should be applied after showering or bathing.

What are the possible side effects of ANDROGEL 1%?

ANDROGEL 1% can cause serious side effects including:

- See **“What is the most important information I should know about ANDROGEL 1%?”**
- **If you already have an enlarged prostate**, your symptoms can get worse while using ANDROGEL 1%. This can include:
 - o increased urination at night.
 - o trouble starting your urine stream.
 - o having to pass urine many times during the day.
 - o having an urge to go to the bathroom right away.
 - o having a urine accident.
 - o 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%.
- **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 ANDROGEL 1% may lower your sperm count.
- Swelling of your ankles, feet, or body, with or without heart failure. This may cause serious problems for people who have heart, kidney or liver disease.
- 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 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.

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.

You can ask your pharmacist or healthcare provider for information about ANDROGEL 1% that is written for health professionals.

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.

Marketed by: AbbVie Inc. North Chicago, IL 60064, USA

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

INSTRUCTIONS FOR USE
ANDROGEL® (AN DROW JEL) CIII
(testosterone gel) 1%
for topical use

Read this Instructions for Use for ANDROGEL 1% 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 ANDROGEL 1%:

- Before applying ANDROGEL 1%, make sure that your shoulders, upper arms or stomach are clean, dry, and there is no broken skin.
- The application sites for ANDROGEL 1% are the shoulders, upper arms or stomach area (abdomen) that will be covered by a short sleeve T-shirt (see Figure A). **Do not** apply ANDROGEL 1% to any other parts of your body such as your penis, scrotum, chest, armpits (axillae), knees, or back.



(Figure A)

- 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.
- **Let the application areas dry completely before putting on a T-shirt.**
- **ANDROGEL 1% is flammable until dry. Let ANDROGEL 1% dry before smoking or going near an open flame.**
- **Wash your hands with soap and water right away** after applying ANDROGEL 1%.
- Avoid showering, swimming, or bathing for at least 5 hours after you apply ANDROGEL 1%.

How should I store ANDROGEL 1%?

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

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