

## USE AND IMPORTANT SAFETY INFORMATION

### USE<sup>1,2</sup>

AndroGel® (testosterone gel) 1% and 1.62% are controlled substances, available by prescription, used to treat adult males who have low or no testosterone due to certain medical conditions.

**It is not known if AndroGel is safe or effective to treat men who have low testosterone due to aging.**

**It is not known if AndroGel is safe or effective in children younger than 18 years old.**

AndroGel is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep it in a safe place to protect it and never give it to anyone else. Selling or giving away this medicine may harm others and is against the law.

**AndroGel is not meant for use in women.**

### IMPORTANT SAFETY INFORMATION<sup>1,2</sup>

- **AndroGel can transfer from your body to others, including children and women.** This can happen if other people come into contact with the area where the AndroGel was applied. Children and women should avoid contact with the unwashed or not covered (unclothed) areas where AndroGel 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.
- Signs and symptoms of early puberty in a child who has come in direct contact with AndroGel 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, including acting aggressively or behaving in an angry or violent way.
- Signs and symptoms in a woman who has come in direct contact with AndroGel may include:
  - Changes in body hair.
  - An abnormal increase in pimples (acne).
- **To lower the risk of transfer of AndroGel 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.
  - 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.
  - 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 child or woman touches the area where you have applied AndroGel, that area on the child or woman should be washed well with soap and water right away.

- **Stop using AndroGel and call your healthcare provider right away if you see any signs and symptoms of puberty in a child, or changes in body hair or increased acne in a woman, that may have happened through accidental touching of the area where you have applied AndroGel.**
- **Do not use AndroGel if you:**
  - Have breast cancer or have or might have prostate cancer.
  - Are pregnant. AndroGel may harm your unborn baby. Women who are pregnant should avoid contact with the area of skin where AndroGel has been applied.
- **Before using AndroGel, tell your healthcare provider about all of your medical conditions, including if you have breast cancer; prostate cancer; urinary problems due to enlarged prostate; heart, kidney, or liver problems; or 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. Especially tell your healthcare provider if you take insulin, medicines that decrease blood clotting (blood thinners), or corticosteroids.
- **AndroGel can cause serious side effects, including:**
  - **If you already have an enlargement of your prostate gland, your signs and symptoms can get worse while using AndroGel** (including changes in urination).
  - **Possible increased risk of prostate cancer.**
  - **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 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.**
  - **Having problems breathing while you sleep (sleep apnea).**
- **The most common side effects of AndroGel 1.62% include** increased prostate specific antigen (a test used to screen for prostate cancer), mood swings, high blood pressure, increased red blood cell count, and skin irritation where the gel is applied.
- **The most common side effects of AndroGel 1% include** acne, skin irritation where AndroGel 1% is applied, lab test changes, and increased prostate specific antigen.
- This is the most important information to know about AndroGel. For further information, talk with your healthcare provider. You may report side effects to ASCEND Therapeutics® US, LLC at [1-877-204-1013](tel:1-877-204-1013).

Please see the full Prescribing Information, including BOXED WARNING, and Medication Guide for AndroGel 1% and please see the full Prescribing Information, including BOXED WARNING, and Medication Guide for AndroGel 1.62%.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov](http://www.fda.gov) /medwatch or call 1-800-FDA-1088.**

**References:** 1. AndroGel 1.62% [package insert]. ASCEND Therapeutics US, LLC, Morristown, NJ. 2022 2. AndroGel 1% [package insert]. ASCEND Therapeutics US, LLC, Morristown, NJ, 2022.

2022AG0009-Revised November 2022