

Your doctor will take a medical history, including an evaluation of conditions that may be causing low testosterone levels. Examples of these conditions include testicular failure due to genetic problems, chemotherapy or problems with the pituitary gland or brain. If you have one of these conditions, your doctor will perform a medical exam, including two blood tests. AndroGel 1.62% should not be used in adult men who have low testosterone as a result of aging alone.

Here are some questions you can ask your doctor:

1. Do I have a medical condition that could cause low testosterone levels?
2. Based on my underlying medical condition, do I need blood tests that measure my total testosterone and the free testosterone in my body?
3. What medical treatment options are available if I have hypogonadism due to a certain medical condition?
4. How does testosterone replacement therapy work?
5. How is AndroGel 1.62% used?
6. Is AndroGel 1.62% right for me?
7. Are there any changes I can make in my diet, fitness, and lifestyle to help address hypogonadism?

Be sure your doctor is aware of any prescription medications, over-the-counter medications, or vitamin supplements you may be taking. In addition, before you use AndroGel 1.62%, tell your doctor if you have breast cancer; prostate cancer; urinary problems due to enlarged prostate; heart, kidney, or liver problems; problems breathing while you sleep (sleep apnea); and/or have any other medical conditions.

## Use and Important Safety Information

### Use<sup>1</sup>

AndroGel® (testosterone gel) 1.62% is a controlled substance, 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 1.62% is safe or effective to treat men who have low testosterone due to aging.**

**It is not known if AndroGel 1.62% is safe or effective in children younger than 18 years old.**

**Testosterone products that are applied to the skin may have different doses, strengths, or application instructions that may lead to different levels of testosterone in your body.**

### Important Safety Information<sup>1</sup>

- 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 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.**

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- **To lower the risk of transfer of AndroGel 1.62%**, you should apply it **only** to your shoulders and upper arms, areas that will be covered by a short-sleeve T-shirt. Wash your hands **right away** with soap and water after applying. After the gel has dried, **cover the application area with clothing** 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.**
- Do not apply AndroGel 1.62% to any other parts of your body, such as your stomach area (abdomen), penis, scrotum, chest, armpits (axillae), or knees.
- **Stop using AndroGel 1.62% 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 occurred through accidental exposure to AndroGel 1.62%.**
- Do not use AndroGel 1.62% if you have breast cancer or have or might have prostate cancer.
- AndroGel 1.62% is not meant for use in women and must not be used in women who are or may become pregnant or are breastfeeding. AndroGel 1.62% may harm the unborn or breastfeeding 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.
- Before you use AndroGel 1.62%, tell your healthcare provider if you have breast cancer; prostate cancer; urinary problems due to enlarged prostate; heart, kidney, or liver problems; problems breathing while you sleep (sleep apnea); or have any other medical conditions.
- **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%** (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**
  - AndroGel 1.62% 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.
  - **In large doses, AndroGel 1.62% 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)**
- Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take insulin, medicines that decrease blood clotting, or corticosteroids.
- AndroGel 1.62% is **flammable** until dry. Let AndroGel 1.62% dry before smoking or going near an open flame.
- **The most common side effects of AndroGel 1.62% are** 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.
- This is the most important information to know about AndroGel 1.62%. For further information, talk with your healthcare provider.

**Reference:** 1. AndroGel 1.62% [package insert]. North Chicago, IL: AbbVie Inc.

Notes: \_\_\_\_\_

Please see [http://www.rxabbvie.com/pdf/androgel1\\_62\\_PI.pdf](http://www.rxabbvie.com/pdf/androgel1_62_PI.pdf) for full Prescribing Information, including Medication Guide, and discuss with your doctor.