**INDICATIONS AND USAGE**

Testosterone gel is an androgen indicated for testosterone replacement therapy in males for:

- Premenopausal testosterone deficiency (see Table 1).
- Male hypogonadism of any etiology (see Table 1).
- Male hypogonadism (primary or secondary) due to chronic renal failure

**DOSAGE FORMS AND STRENGTHS**

Testosterone gel is available in 2.5 mg, 5 mg, 10 mg, and 20 mg dispensing units.

**CONTRAINDICATIONS**

- Known hypersensitivity to any component of the formulation
- Breast cancer

**WARNINGS AND PRECAUTIONS**

- Cardiovascular disease
- Hypertension
- Edema
- Venous thromboembolism
- Sleep apnea
- Venous thromboembolism
- Polycythemia
- Gynecomastia
- Venous thromboembolism

**DRUG INTERACTIONS**

- Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

**ADVERSE REACTIONS**

- The most common adverse reactions to testosterone gel are:
  - Headache
  - Back pain
  - Hemorrhoids
  - Acne

**WARNING: SECONDARY EXPOSURE TO TESTOSTERONE**

- Changes in anticoagulant activity may be seen with androgens. More frequent monitoring of the International Normalized Ratio (INR) and prothrombin time is recommended in patients taking anticoagulants.

**NOTES**

- Most common adverse reactions to testosterone gel are:
  - Headache
  - Back pain
  - Hemorrhoids
  - Acne

**FULL PRESCRIBING INFORMATION: CONTENTS**

1. INDICATIONS AND USAGE
2. DOSAGE AND ADMINISTRATION
3. CONTRAINDICATIONS
4. WARNINGS AND PRECAUTIONS
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8. WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

**TABLE 1: Incidence of Adverse Reactions (Reported by ≥1% of the Testosterone Gel Patients and greater than placebo)**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Testosterone Gel (n=99)</th>
<th>Placebo Gel (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Back pain</td>
<td>8%</td>
<td>1%</td>
</tr>
<tr>
<td>Hemorrhoids</td>
<td>6%</td>
<td>1%</td>
</tr>
<tr>
<td>Acne</td>
<td>5%</td>
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Serious adverse reactions have been reported in individuals who abuse androgens, and include respiratory depression, decreased level of consciousness, coma, and death. These reactions result from the rapid increase in testosterone concentration during self-administration of androgens. Patients who abuse androgens may demonstrate bradycardia and/or hypotension, which may lead to a false impression of hypovolemia. This impression may be compounded by the fact that many individuals who abuse anabolic androgenic steroids also abuse alcohol, which can mask the bradycardia and hypotension associated with the androgen-induced hypovolemia.