

# Testosterone Undecanoate

MADE IN GERMANY

Solution for Injection



1000 mg  
4 ml

Testosterone undecanoate is a long-acting testosterone preparation for the treatment of male hypogonadism where testosterone deficiency has been confirmed by clinical symptoms and biochemical tests.

- **Ready to use** injectable solution which forms a slow-release Depot after intramuscular injection
- **Patient convenient** long-acting oil-based formulation requiring less frequent administration to achieve clinical benefits and stable testosterone levels
- Available in both **vials and ampoules**



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<b>Indications</b>	Testosterone undecanoate is indicated for testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.
<b>Active Ingredient</b>	Testosterone undecanoate
<b>Excipients</b>	Benzyl benzoate, Castor oil
<b>Presentation</b>	<b>1000 mg/4 ml</b> solution for injection
<b>Strength</b>	Each 1 ml solution for injection contains 250 mg testosterone undecanoate corresponding to 157.9 mg testosterone.
<b>Stability</b>	<b>Unopened:</b> 24 months, does not require any special storage conditions The medicinal product must be used immediately after first opening.
<b>Primary Packaging</b>	<ul style="list-style-type: none"><li>■ 5-ml amber glass (type I) ampoules, containing a fill volume of 4 ml.</li><li>■ 5-ml amber glass (type I) vial with a bromobutyl rubber stopper and an aluminium cap containing a fill volume of 4 ml.</li></ul>
<b>Pack sizes</b>	1 ampoule or 1 vial per pack

**Testosterone undecanoate EVER Pharma 1000 mg/4 ml, solution for injection.** Composition: One ml solution for injection contains 250 mg Testosterone undecanoate corresponding to 157.9 mg testosterone. List of excipients: Benzyl Benzoate, Castor Oil, Refined. Therapeutic Indications: Testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. Contraindications: The use of Testosterone undecanoate is contraindicated in men with androgen-dependent carcinoma of the prostate or of the male mammary gland, past or present liver tumours hypersensitivity to the active substance or to any of the excipients (listed in section 6.1). The use of Testosterone undecanoate in women is contraindicated. Adverse reactions: Common: Polycythaemia, Haematocrit increased, Red blood cell count increased, Haemoglobin increased, Weight increased, Hot flush, Uncommon: Cardiovascular disorder, Hypertension, Dizziness, Acne, Prostate specific antigen increased, Prostate examination abnormal, Benign prostate hyperplasia, Various kinds of injection site reactions. Uncommon: Hypersensitivity Increased appetite, Glycosylated haemoglobin increased, Hypercholesterolaemia, Blood triglycerides increased, Blood cholesterol increased, Depression, Emotional disorder, Insomnia, Restlessness, Aggression, Irritability, Headache, Migraine, Tremor, Bronchitis, Sinusitis, Cough, Dyspnoea, Snoring, Dysphonia, Diarrhoea, Nausea, Liver function test abnormal, Aspartate aminotransferase increased, Alopecia Erythema, Rash, Pruritus, Dry skin, Arthralgia, Pain in extremity, Muscle disorders, Musculoskeletal stiffness, Blood creatine phosphokinase increased, Urine flow decreased, Urinary retention, Urinary tract disorder, Nocturia, Dysuria, Prostatic dysplasia, Prostate induration, Prostatitis, Prostatic disorder, Libido changes, Testicular pain, Breast induration, Breast pain, Gynaecomastia, Oestradiol increased, Testosterone increased, Fatigue, Asthenia, Hyperhidrosis. Rare: Pulmonary oil micro embolism. More information available in the summary of product characteristics. Only available on prescription. Last update: December 2023. Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria.