

Testosterone Undecanoate

Solution for Injection

MADE IN GERMANY



1000 mg
4 ml

Testosterone Undecanoate EVER Pharma is a long-acting oil-based testosterone preparation, available in vials, forming a slow-release depot after intramuscular (IM) injection.

It is indicated for testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.

- **Long-acting depot** – one of the longest-acting injectable testosterone esters in clinical use, forming a slow-release depot after intramuscular injection
- **Oil-based Solution** – ensures slow, controlled absorption following intramuscular injection



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Indications	Indicated for testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.
Active Ingredient	Testosterone undecanoate
Excipients	Benzyl benzoate, Castor oil
Presentation	1000 mg/4 ml solution for injection
Strength	Each 1 ml of solution contains 250 mg testosterone undecanoate, equivalent to 157.9 mg testosterone.
Stability	■ Unopened: 24 months. No special storage conditions required. ■ After 1st Opening: The medicinal product must be used immediately after first opening.
Primary Packaging	■ Type I amber glass 5 ml vial with a rubber stopper, sealed with an aluminium cap covered with a flip-off cap.
Pack sizes	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.