

VERTEX PHARM

TESTOSTERONE ENANTHATE

250 mg/mL

Solution for injection | Sterile oily solution | Multi-dose vial

FOR DEEP INTRAMUSCULAR USE ONLY | PRESCRIPTION MEDICINE

PRODUCT DETAILS

Strength: 250 mg/mL.**Active substance:** Each 1 mL contains 250 mg testosterone enanthate.**Excipients:** [CARRIER OIL]; [PRESERVATIVE(S) AND QUANTITY]; [OTHER EXCIPIENTS].**Vial:** [VIAL VOLUME] mL; [TOTAL AMOUNT] mg per vial.**Form:** Sterile, clear, colourless to pale-yellow oily solution for injection.**Route:** Deep intramuscular use only. Not for intravenous use. Do not use subcutaneously unless authorised.**Chemical data:** C₂₆H₄₀O₃; molecular weight 400.59 g/mol; CAS 315-37-7.**Status:** Prescription medicine. [CONTROLLED-DRUG MARK].DESCRIPTION /
PHARMACOLOGY

Testosterone enanthate is a long-acting testosterone ester in an oily depot. It is gradually released and hydrolysed to testosterone. Testosterone supports male reproductive tissues, secondary sexual characteristics, libido, muscle, bone and erythropoiesis; it suppresses pituitary gonadotropins and may suppress spermatogenesis.

Pharmacokinetics: Oil-based esters are slowly absorbed. Testosterone is protein bound, metabolised mainly in the liver and eliminated predominantly in urine.

INDICATIONS

Replacement therapy in adult males with confirmed primary or hypogonadotropic hypogonadism, supported by symptoms and low morning serum testosterone on two separate days. Not established for age-related hypogonadism. Not for bodybuilding, performance enhancement, cosmetic use or infertility. [USE THE EXACT SWISSMEDIC-AUTHORISED INDICATION].

DOSAGE AND ADMINISTRATION

For administration by a qualified healthcare professional. Individualise dose and interval according to the approved product information, serum testosterone, response and adverse reactions. Use aseptic technique and a new sterile needle and syringe. Inject slowly and deeply into the gluteal muscle, avoiding intravascular injection; rotate sites. Before use verify product, strength, dose, patient, route, EXP and LOT; inspect and record administration.

MULTI-DOSE VIAL

Disinfect the stopper and allow it to dry. Use a new sterile needle and syringe for every withdrawal. Do not leave a needle in the stopper, pool residues or transfer contents. Record first puncture and every withdrawal. Discard [IN-USE PERIOD] after first puncture, or sooner if contamination or closure damage is suspected, according to validated in-use stability.

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CONTRAINDICATIONS

Known or suspected prostate or male-breast carcinoma; pregnancy or possible pregnancy; hypersensitivity to testosterone enanthate or any excipient, including carrier oil or preservative;

[OTHER PRODUCT-SPECIFIC CONTRAINDICATIONS].

WARNINGS AND PRECAUTIONS

Polycythaemia: Testosterone may increase haemoglobin/haematocrit; check periodically and adjust or interrupt treatment when indicated.

Blood pressure/CV risk: Monitor blood pressure and reassess if cardiovascular disease or risk factors develop.

Prostate/BPH: Assess prostate-cancer risk before treatment and monitor according to age and risk; watch for worsening urinary symptoms.

VTE: Leg pain, swelling, warmth or redness may indicate DVT; sudden chest pain or breathlessness may indicate pulmonary embolism. Discontinue and investigate if suspected.

Fluid retention: Oedema, with or without heart failure, may occur, especially with cardiac, renal or hepatic disease.

Oil-injection reaction: Rare immediate urge to cough, coughing fits or respiratory distress may occur. Stop injection and assess.

Other: May worsen sleep apnoea, suppress fertility and cause gynaecomastia or prolonged erections. Jaundice or abnormal liver tests require assessment. Misuse or combination with

anabolic steroids may cause serious cardiovascular, hepatic, endocrine and psychiatric harm.

MONITORING

Monitor response and appropriately timed serum testosterone. Periodically assess haemoglobin/haematocrit, blood pressure, prostate/PSA as appropriate, lipids, liver function and signs of oedema, sleep apnoea, VTE or mood change. In diabetes, monitor glucose.

DRUG INTERACTIONS

Oral anticoagulants: monitor coagulation when testosterone is started, stopped or adjusted. Insulin/antidiabetics: requirements may decrease.

ACTH/corticosteroids: oedema risk may increase. Androgens may alter thyroid-binding globulin and laboratory values.

ADVERSE REACTIONS

Injection-site pain/inflammation; acne or oily skin; hair changes; libido change; headache, anxiety or depression; gynaecomastia; frequent/prolonged erections; oligospermia/infertility; fluid retention; increased blood pressure or haematocrit; altered lipids; nausea; jaundice or abnormal liver tests. Serious reactions include myocardial infarction, stroke, VTE, severe oedema/heart failure, polycythaemia, hepatic injury, anaphylactoid reactions and prolonged painful erection.

URGENT MEDICAL HELP

Seek urgent care for chest pain; sudden breathlessness; cough/respiratory distress during injection; one-sided leg swelling; stroke symptoms; severe allergy; jaundice; or a prolonged painful erection.

STORAGE / PRESENTATION

Storage: [APPROVED TEMPERATURE RANGE]. Protect from light. [OTHER APPROVED CONDITIONS]. Keep in original pack, out of children's sight and reach. Do not use after EXP.

Presentation: [VIAL VOLUME] mL multi-dose vial; pack [NUMBER]. Discard [IN-USE PERIOD] after first puncture under [APPROVED CONDITIONS].

COMPANY / TRACEABILITY

Company: Vertex Pharm, Baarerstrasse 23, CH-6300 Zug, Switzerland.

Website: vertex-pharmacy.com

Manufacturer: [LEGAL NAME AND ADDRESS].

Authorisation: [SWISSMEDIC NUMBER / PACK CODE].

Safety reports: [PHONE / EMAIL].

Variable data: LOT [] MFG []
EXP [] GTIN [].