

Prescribing Information Testogel® (testosterone)

40.5mg, transdermal gel in sachet

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SmPC).

Presentation: 2.5 g sachets containing 40.5 mg of testosterone. 1.81g alcohol (ethanol) in each sachet of 2.5g.

Indication: In adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.

Posology and method of administration: Adult and elderly men. Each sachet provides a dose of 2.5 g of gel (i.e. 40.5 mg of testosterone). The entire contents of one sachet should be applied once daily at about the same time, preferably in the morning. The daily dose should be adjusted up or down depending on the clinical or laboratory response in individual patients, not exceeding 81 mg of testosterone per day (2 sachets i.e. 5 g of gel). The adjustment of posology should be achieved by approximately 1.25 g of gel (half sachet) steps. Transdermal use. The gel should be administered by the patient himself, onto clean, dry, healthy skin over right and left upper arms and shoulders. Allow drying for at least 3–5 minutes before dressing. Wash hands with soap and water after each application. Do not apply to the genital areas as the high alcohol content may cause local irritation.

Contraindications: cases of known or suspected prostatic cancer or breast carcinoma, known hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions for use: Testosterone insufficiency should be clearly demonstrated by clinical features and confirmed by 2 separate blood testosterone measurements. Testosterone level should be monitored at baseline and at regular intervals during treatment. In patients receiving long-term androgen treatment the following laboratory parameters should be checked regularly: haemoglobin, haematocrit (to detect polycythaemia), liver function tests and lipid profile. Risk of pre-existing prostatic cancer should be excluded, and the prostate gland and breast monitored during Testogel treatment. Androgens may accelerate the progression of sub-clinical prostatic cancer. Testogel should be used with caution in cancer patients at risk of hypercalcaemia and associated hypercalciuria due to bone metastases; regular monitoring of serum calcium concentrations is recommended in these patients. In patients suffering from severe cardiac, hepatic or renal insufficiency or ischaemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac failure. In such case, treatment must be stopped immediately. Testosterone may cause a rise in blood pressure and should be used with caution in men with hypertension. Testogel should be used with caution in patients with thrombophilia or risk factors for venous thromboembolism. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dosage adjustment. Testogel should be used with caution in patients with epilepsy and migraine as these conditions may be aggravated. In case of severe application site reactions,

treatment should be reviewed and discontinued if necessary. Testogel can be transferred to other persons by close skin to skin contact. There is limited experience regarding safety and efficacy of Testogel in patients over 65 years of age. With large doses of exogenous androgens, spermatogenesis may be suppressed which could possibly lead to adverse effects on semen parameters including sperm count. Testogel is not indicated for use in women or in children under 18 years of age. For further details refer to the SmPC.

Interactions: Increased effect of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. Testogel may affect results of laboratory tests of thyroid function. In diabetic patients, the dose of antidiabetic medications may need reduction.

Pregnancy and lactation: Pregnant women must avoid any contact with Testogel application sites. This product may have adverse virilising effects on the foetus. Spermatogenesis may be reversibly suppressed with this medicine.

Effect on ability to drive and use machines: No or negligible influence.

Undesirable effects: The most frequently observed adverse drug reactions at the recommended dosage of gel per day were skin reactions: reaction at the application site, erythema, acne, dry skin. Common; mood disorders, dizziness, paraesthesia, amnesia, hyperaesthesia, hypertension, diarrhoea, alopecia, urticaria, gynaecomastia, mastodynia, prostatic disorders, headache, changes in laboratory tests (polycythaemia, lipids), haematocrit increased, red blood count increased, haemoglobin increased. Prescribers should consult the SmPC in relation to other adverse reactions.

Overdose: Symptom may include application site rash. Serum testosterone levels should be measured if clinical signs and symptoms indicative of overexposure to androgen are observed.

NHS Price: £31.11 per 30 sachets. **Legal category:** POM.

Marketing Authorisation Number: PL

42714/0005. **Marketing Authorisation Holder:** Besins Healthcare (UK) Ltd, Lion Court, 25 Procter Street, Holborn, London, WC1V 6NY, UK. **Date of preparation of Prescribing Information:** February 2024 TES/2024/012

Adverse events should be reported

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 0203 862 0920
Email: pharmacovigilance@besins-healthcare.com