PRESCRIBING INFORMATION TESTOGEL®(testosterone) 16.2 MG/G, GEL

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

Presentation: Transparent or slightly opalescent, colourless transdermal gel in a multi-dose container, one pump actuation delivers 1.25g of gel containing 20.25g of testosterone. **Indication:** In adults for testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Dosage and administration:** Transdermal use. The recommended dose is two pump actuations of gel (i.e., 40.5 mg of testosterone) applied once daily at about the same time, preferably in the morning. The daily dose should be adjusted by the physician depending on the clinical or laboratory response in individual patients, not exceeding four pump actuations or 81 mg testosterone per day. The adjustment of posology should be achieved by increments of one pump actuation of gel, usually based on measurements of blood testosterone levels and/or clinical response. The gel should be administered by the patient himself, onto clean, dry, healthy skin over both shoulders, or both arms. Do not apply to the genital areas as the high alcohol content may cause local irritation. **Contraindications**: Cases of known or suspected prostate cancer or breast carcinoma. Cases of known hypersensitivity to testosterone or to any of the excipients. **Warnings and precautions for use:** Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by 2 separate blood testosterone measurements. Testosterone levels should be monitored at baseline and at regular intervals during treatment. In patients receiving long-term androgen therapy, the following laboratory parameters should also be monitored regularly: haemoglobin, and haematocrit (to detect polycythaemia), liver function tests, and lipid profile. This medicine may affect results of laboratory tests of thyroid function. Risk of pre-existing prostatic cancer should be excluded and the prostate gland and breast monitored during this medicines treatment. Androgens may accelerate the progression of sub-clinical prostate cancer and benign prostate hyperplasia. This medicine should be used with caution in cancer patients at risk of hypercalcaemia (and associated hypercalciuria) due to bone metastases; regular monitoring of blood calcium levels is recommended in these patients. In patients suffering from severe cardiac, hepatic or renal insufficiency, or ischaemic 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. In addition, diuretic therapy may be required Testosterone may cause a rise in blood pressure and should be used with caution in men with hypertension. This medicine should be used with caution in patients with thrombophilia or risk factors for venous thromboembolism (VTE), as there have been post- marketing reports of thrombotic events in these patients during testosterone therapy. In thrombophilic patients, VTE cases have been reported even under anticoagulation treatment, therefore continuing testosterone therapy after first thrombotic event should be carefully evaluated. In case of treatment continuation, further measures should be taken to minimise the individual VTE risk. Gynaecomastia occasionally develops and occasionally persists. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dosage adjustment. This medicine should be used with caution in patients with epilepsy and migraine as these conditions may be aggravated. If the patient develops a severe application site reaction, treatment should be re-evaluated and discontinued if necessary. This medicine is flammable until dry. This medicine can be transferred to other persons by close physical contact at any time after dosing. Additional caution should be taken when using this product and in close physical contact with children as secondary transmission of testosterone through clothing cannot be excluded. The physician should inform the patient carefully about the risk of testosterone transfer. Before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 1 hour) has passed and cover again with clean clothing. This product contains ethanol: in neonates, high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin. This medicine is not indicated for use in women or in children under 18 years of age. **Interactions:** Patients receiving oral anticoagulants require close monitoring especially when androgens are started or stopped. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. Interactions with laboratory tests: androgens may decrease levels of thyroxin binding globulin. This medicine may cause changes in insulin sensitivity, glucose tolerance, glycaemic control, blood glucose and glycosylated haemoglobin levels have been reported with androgens. In diabetic patients, antidiabetic medication might need dose reduction. **Fertility, pregnancy and lactation:** Pregnant women must avoid any contact with this medicines application sites. This product may have adverse virilising effects on the foetus. Spermatogenesis may be reversibly suppressed with this medicine. This medicine is intended for men only. This medicine is not indicated in women who are breast-feeding. **Effects on ability to drive and use machines:** No studies on the effects on the ability to drive and use machines have been performed. **Undesirable effects:** The most frequently observed clinical adverse drug reactions at the recommended dosage per day were skin reactions at the application site, (erythema, acne, dry skin), anxiety and asthenia. Skin reactions include: acne, alopecia, dry skin, skin lesions, contact dermatitis, hair colour changes, rash, application site hypersensitivity, application site pruritus. Common adverse reactions (≥1/100; <1/10): occur with this medicine: mood disorders, emotional symptoms, dizziness, amnesia, hyperaesthesia, headache, diarrhoea, alopecia, urticaria, gynaecomastia, application site reactions, increased haematocrit, increased haemoglobin, red cell count increased. Uncommon adverse reactions (≥1/1000 to <1/100): occur with this medicine: malignant hypertension, flushing, phlebitis, abdominal distention, oral pain, acne, hirsutism, rash, dry skin, seborrhoea, skin lesions, contact dermatitis, hair colour changes, application site hypersensitivity/pruritis, nipple disorder, prostate abnormality, testicular pain, increased erection, pitting oedema and prostate specific antigen (PSA) increased. Please refer to the SmPC for further information. **Overdose**: Treatment of overdosage consists of washing the application site immediately and discontinuing treatment if advised by the treating physician **NHS Price:** £39.94 per 88g pump pack. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0007. **Marketing Authorisation Holder:** Besins Healthcare, Rue Washington 80, 1050 Ixelles, Belgium. **Date of preparation of Prescribing Information:** January 2025 MAT-PROMO-TES-0127

Adverse events should be reported.

Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/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 or Email: pharmacovigilance@besins-healthcare.com

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. The recommended dose is 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 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 in 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 both shoulders or both arms. Allow drying for at least 3–5 minutes before dressing. Wash hands thoroughly with soap and water after applying the gel. Before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 1 hour) has passed and cover the site again with clean clothing. 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 deficiency 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 hypercalcemia 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. In addition, diuretic therapy may be required. 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 physical contact. With large doses of exogenous androgens, spermatogenesis may be reversibly 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. The gel can be transferred to other persons by close physical contact at any time after dosing. Additional caution should be taken in close physical contact with children as secondary transmission of testosterone through clothing cannot be excluded. This product contains ethanol: in neonates, high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin. 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**. Fertility, 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. This medicine is not indicated in women who are breast-feeding. **Effect on ability to drive and use machines:** No studies on the effects on the ability to drive and use machines have been performed **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, emotional symptoms. Common (≥1/100 to<1/10); mood disorders, dizziness, paraesthesia, amnesia, hyperaesthesia, hypertension, diarrhoea, alopecia, urticaria, gynaecomastia, headache, changes in laboratory tests (polycythaemia, lipids), haematocrit increased, red blood count increased, haemoglobin increased. Uncommon (≥1/1,000 to ≥1/100) malignant hypertension, flushing, phlebitis, oral pain, abdominal distension, acne, hirsutism, rash, dry skin, seborrhoea, skin lesions, contact dermatitis, hair colour changes, application site hypersensitivity/ pruritis, nipple disorder, prostate abnormalities, testicular pain, increase erections, pitting oedema, PSA increased. Please refer to the SmPC for further information. **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: £39.94 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:** January 2025 MAT-PROMO-TES-0128

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