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 (SPC).

Presentation: Transdermal gel in a multi-dose container, one pump actuation delivers 1.25g of gel containing 20.25mg of testosterone. **Indication:** In adults as 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 doctor 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 on the right and left upper arms and shoulders. 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 insufficiency 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 addition to laboratory analyses of testosterone levels 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. Testogel 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 Testogel treatment. Androgens may accelerate the progression of sub-clinical prostate cancer and benign prostate hyperplasia. Testogel 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. Testogel should be used with caution in patients with ischaemic heart disease. 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 (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. Testogel 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. Testogel is flammable until dry. 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. Testogel is not indicated for use in women or in children under 18 years of age. Testogel is not a treatment for male impotence or sterility. **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. Testogel may cause changes in insulin sensitivity, glucose tolerance, glycaemic control, blood glucose and glycosylated haemoglobin levels have been reported with androgens. In diabetic patients, antidiabetics' medication might 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. **Undesirable effects:** The most frequently observed clinical adverse drug reactions observed with Testogel 16.2mg/g used at the recommended dosage were psychiatric disorders and skin reactions at the application site. Local skin reactions include: acne, alopecia, dry skin, skin lesions, contact dermatitis, hair colour changes, rash, application site hypersensitivity, application site pruritus. The following commonly (≥1/100; <1/10) occur with Testogel: emotional symptoms, prostate specific antigen (PSA) increased, increased haematocrit, increased haemoglobin. The following uncommonly (≥1/1000 to <1/100) occur with Testogel: malignant hypertension, flushing, phlebitis, diarrhoea, abdominal distention, oral pain, gynaecomastia, nipple disorder, testicular pain, increased erection and pitting oedema.

NHS Price: £31.11 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:** June 2022 TES/2022/039

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 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. 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 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. 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