# PRESCRIBING INFORMATION Testavan® 20 mg/g

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

**Presentation:** One gram of gel contains 20 mg testosterone. One pump actuation delivers 1.15 g (1.25 mL) of gel equivalent to 23 mg of testosterone. One gram of gel contains 0.2 g of propylene glycol. Testavan® is a homogenous, translucent, slightly opalescent gel. **Indication:** Testosterone replacement therapy for adult male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Dosage and administration:** Recommended starting dose: 23mg testosterone (one pump actuation) applied once daily. The maximum recommended dose is 69mg testosterone per day, which is equivalent to 3 pumps actuations. The serum testosterone level should be measured 2-4 hours after dosing approximately 14 days and 35 days after starting treatment or after a dose adjustment. If the serum testosterone concentration is below 17.3nmol/L (500ng/dL), the daily Testavan® dose may be increased by one pump actuation. If the serum testosterone concentration exceeds 36.4 nmol/L (1050 ng/dL), the daily Testavan® dose may be decreased by one pump actuation. Testavan® should be applied to the upper arm and shoulder, using the applicator. Patients should be instructed to prime Testavan® as per the Patient Information Leaflet. Patients should be instructed not to apply Testavan® with their hands. After use, the applicator should be cleaned with a tissue and the protective lid restored on top of the applicator. Not for use in women or children. Not clinically evaluated in males less than 18 years of age. **Contraindications:** Hypersensitivity to the active substance, propylene glycol or to any of the excipients. Known or suspected carcinoma of the breast or the prostate. Warnings and precautions for use: Prior to therapy the risk of prostate cancer must be excluded. Examine breast and prostate gland at least yearly and twice yearly in the elderly or at risk patients (those with clinical or familial factors). Monitor serum calcium levels in patients with skeletal metastases at risk of hypercalcaemia/hypercalciuria. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dosage adjustment. Testosterone may cause rise in blood pressure and Testavan® should be used with caution in men with hypertension. In patients suffering from severe cardiac, hepatic or renal insufficiency, or ischemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac failure. In this case, treatment must be stopped immediately. Testosterone should be used with caution in patients with thrombophilia and in patient with ischemic heart disease, epilepsy, and migraine as these conditions may be aggravated. Possible increased risk of sleep apnoea in patients who are obese or with chronic respiratory disease. Improved inulin sensitivity may occur. Periodically monitor testosterone concentrations, full blood count, lipid profile, and liver function. Patients are advised not to wash or shower for at least 2 hours patient about the transfer risk, which can be prevented by covering or washing the site before contact. Pregnant women must avoid any contact with Testavan® application sites. Testavan® should not be prescribed for patients who may not comply with safety instructions (e.g severe alcoholism, drug abuse, severe psychiatric disorders). The content of the tube Is flammable; therefore avoid fire, flame or smoking until the gel has dried. Testavan® contains propylene glycol which may cause skin irritation. If severe application site reaction occurs, treatment should be reviewed and discontinued is necessary. **Special precautions for storage:** No special storage conditions. **Interactions:** When androgens are given simultaneously with anticoagulants, the anticoagulant effects can increase. Patients receiving oral anticoagulants require close monitoring of their international normalized ratio (INR) especially when androgen treatment is started or stopped. The concurrent administration of testosterone with adrenocorticotropic hormone (ACTH) or corticosteroids may increase likelihood of oedema; thus these drugs should be administered with caution, particularly in patients with cardiac, renal or hepatic disease. Improved insulin sensitivity may occur in patients treated with androgens who achieve normal testosterone plasma concentrations following replacement therapy. Interaction studies with body lotion and sunscreen products have not been performed **Undesirable effects:** The most frequently observed clinical adverse drug reactions observed with Testavan® 20 mg/g Transdermal gel used at the recommended dosage in phase 2 and phase 3 clinical trials lasting up to 9 months were application site reactions (4%) including: rash, erythema, pruritus, dermatitis, dryness, and skin irritation. The majority of these reactions were mild to moderate in severity. The following commonly (≥1/100; <1/10) occur with Testavan®: application site reaction, Blood triglycerides increased/hypertriglyceridemia, haematocrit increased, prostate specific antigen (PSA) increased, increased haematocrit. The following uncommonly (≥1/1000 to <1/100) occur with Testavan®: Haemoglobin increased, headaches.

**NHS Price:** £25.22 85.5g pump pack, £75.22 3 x 85.5g pack. **Legal category:** POM**. Marketing Authorisation Number:** PL54460/0002 **Marketing Authorisation Holder:** The Simple Pharma Company UK Limited, 1 Duchess St., Paddington, West End, London, W1W 6AN. **Date of preparation of Prescribing Information:** September 2024 INFO_4348_UK_HCP

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to pharmacovigilance@simplepharma.com