Prescribing Information: Testavan® (testosterone 20mg/g gel)

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Testavan® (testosterone 20 mg/g gel) **Composition:** 20mg/g testosterone transdermal gel. 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. Testavan® is a homogenous, translucent to 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: 23 mg testosterone (one pump actuation) applied once daily. The maximum recommended dose is 69 mg testosterone per day, which is equivalent to 3 pump 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 17.3 nmol/L (500 ng/dL), the daily Testavan® dose may be increased by 1 pump actuation. If the serum testosterone concentration exceeds 36.4 nmol/L (1050 ng/dL), the daily Testavan® dose may be decreased by 1 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 fingers or 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 and 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 prostate. **Special Warnings and Precautions:** Prior to therapy, the risk of prostate cancer must be excluded. Examine breast and prostate gland at least yearly and twice yearly in 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 a 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 ischaemic 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 patients 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 insulin 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 after applying Testavan®. The gel may be transferred to others by skin to skin contact, which could lead to adverse reactions (inadvertent androgenisation) by repeated contact. Inform the 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® gel 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 if necessary. **Side effects:** *Common* (1% to <10%): Application site reactions (rash, erythema, pruritus, dermatitis, dryness, skin irritation), increased blood triglycerides/hypertriglyceridaemia, increased PSA, increased haematocrit, hypertension; *Uncommon* (0.1% to <1%): increased haemoglobin, headache. Some of the other known reactions to testosterone include: anaemia, insomnia, dizziness, hot flushes, dyspnoea, nausea, musculoskeletal pain, gynaecomastia, weight increase, elevated PSA, elevated haematocrit, red blood cell count increased or elevated haemoglobin. Please consult the full Summary of Product Characteristics for further information about side effects. **Special precautions for storage:** No special storage conditions. **Presentation:** Multidose container consisting of a metering pump with a laminate foil pouch in a bottle, and is provided with a cap applicator with a hygienic lid. Each pump contains 85.5 g Testavan® gel and is capable of dispensing 56 metered doses. **Marketing Authorisation Number:** 03194/0127 **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal category:** POM. **Basic NHS price:** £26.64 **Date of preparation:** August 2018 **Testavan® is a registered trademark. PI Job Code:** TSV/2182/2018/UK 2018

Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**
Adverse events should also be reported to Ferring Pharmaceuticals Ltd.
Tel: 0800 111 4126. Email: **medical@ferring.com**