Testavan®

20 mg/g transdermal gel
testosterone

2% TESTOSTERONE GEL
to treat adult hypogonadism[1]

Reference: 1. TESTAVAN® SmPC, 2019; available at www.andro-labs.com/our-products.

CLINICAL SIGNS AND SYMPTOMS SUGGESTIVE OF HYPOGONADISM[1]

COGNITIVE AND PSYCHOLOGICAL[1]

Hot flushes | Anger | Fatigue | Changes in mood, depression | Sleep disturbances | Diminished cognitive function

METABOLIC[1]

Metabolic syndrome | Insulin resistance | Type 2 diabetes mellitus | Visceral obesity

SKELETAL[1]

Decrease in bone mineral density (osteoporosis) with low trauma fractures

SEXUAL[1]

Reduced sexual desire and activity | Erectile dysfunction | Fewer and diminished nocturnal erections

MUSCULAR[1]

Decrease in lean muscle mass and strength

PHYSICAL[1]

Gynaecomastia | Reduced testis volume | Decreased body hair

HAEMATOLOGICAL[1]

Mild anaemia

Hypogonadism in adult men often remains undiagnosed and untreated[2]

ADULT MALE HYPOGONADISM SHOULD BE CONFIRMED BY CLINICAL FEATURES AND BIOCHEMICAL TESTS[1,2]

CLINICAL FEATURES[1,2] • Conduct a full physical examination for signs of hypogonadism. Exclude systemic illnesses, signs of malnutrition and malabsorption, and ongoing acute disease.

BIOCHEMICAL TESTS[1,2] • Measure total testosterone on at least two occasions with a reliable method*

TREATMENT GUIDELINES[1,2]

Testosterone Symptoms			
Low (<8 nmol/L)†	Yes	→	Treat based on clinical judgement
Lower normal (8-12 nmol/L)†	Yes	(+ Measure free testosterone <0.225 nmol/L†) →	Consider a trial of testosterone therapy for a minimum of 6 months based on symptoms
Normal (>12.1 nmol/L)†	—	→	Treatment not required

Men with confirmed hypogonadism can benefit from treatment of comorbidities, lifestyle modifications and TRT[1,2]

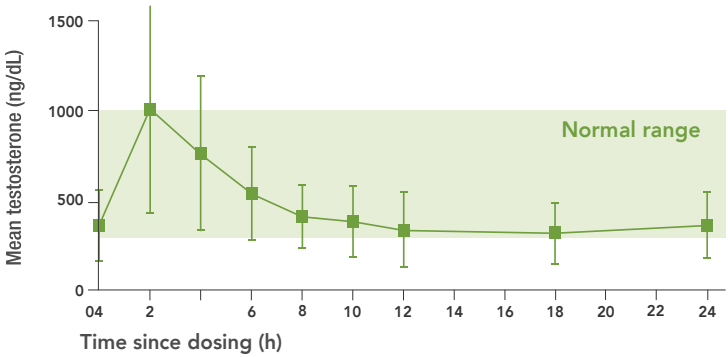
*In most cases two morning (7:00 am to 11:00 am) samples (during fasting state) are sufficient, but should trigger further evaluation if the difference is >20%. †Testosterone unit conversion: 1.0 nmol/L=28.84 ng/dL. TRT, testosterone replacement therapy.

References 1. Dohle G et al. EAU Guidelines on Male Hypogonadism 2018. Available at: http://uroweb.org/guideline/male-hypogonadism/.
2. Trinick TR et al. Aging Male 2011;14(1):10–15.

TESTAVAN® RESTORES PLASMA TESTOSTERONE LEVELS AND MIRRORS MEN'S NATURAL DIURNAL RHYTHM[1,2]

76% to 86%
of men achieved normalised testosterone by month 3 in pivotal and supportive clinical trials[1,4]

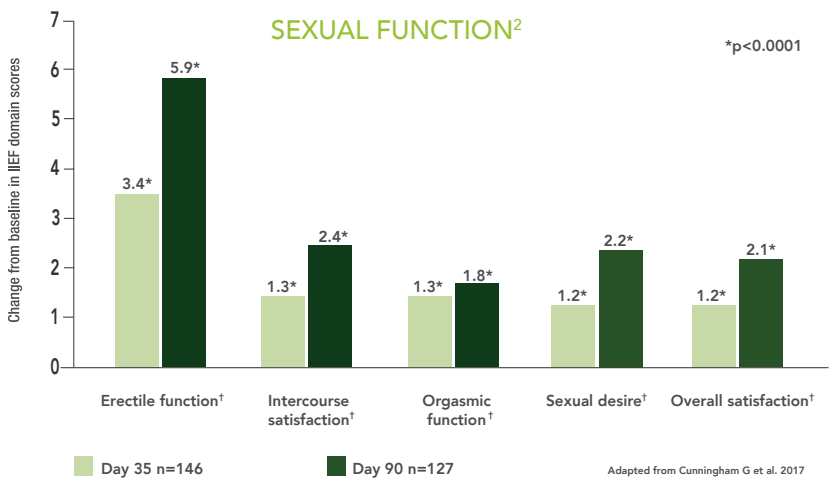
MEAN (±SD) SERUM CONCENTRATIONS OF TESTOSTERONE ON DAY 90 AFTER TESTAVAN® DOSE 4 TITRATION IN PIVOTAL PHASE 3 STUDY[3]



TESTAVAN® restores men's natural testosterone diurnal rhythm, reducing clinical symptoms of hypogonadism and incidence of supraphysiological testosterone levels[2–4]

TESTAVAN® OFFERS RAPID AND SUSTAINED IMPROVEMENTS IN SEXUAL FUNCTION, FATIGUE AND OVERALL QOL[1,2]

SEXUAL FUNCTION[2]



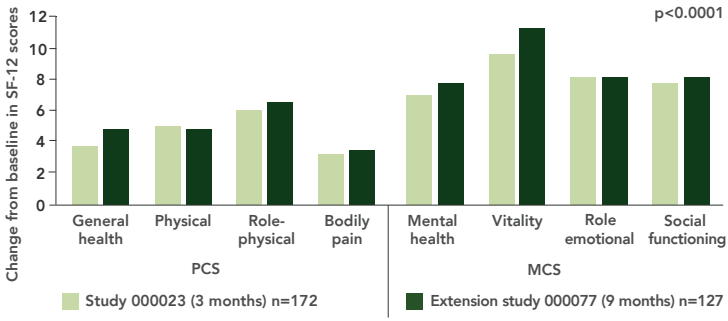
Significant increase in sexual desire and erectile function at 1 and 3 months (p<0.0001) in the TESTAVAN® pivotal study[1]

QOL Quality of life

References 1. Belkoff L et al. Andrologia 2018;50(1):e12801. 2. Cunningham G et al. Endocr Pract 2017;23(5):557–565. 3. TESTAVAN® SmPC The Simple Pharma Company. 4. Arver S et al. Andrology 2018;6(3):396–407.

OVERALL QOL

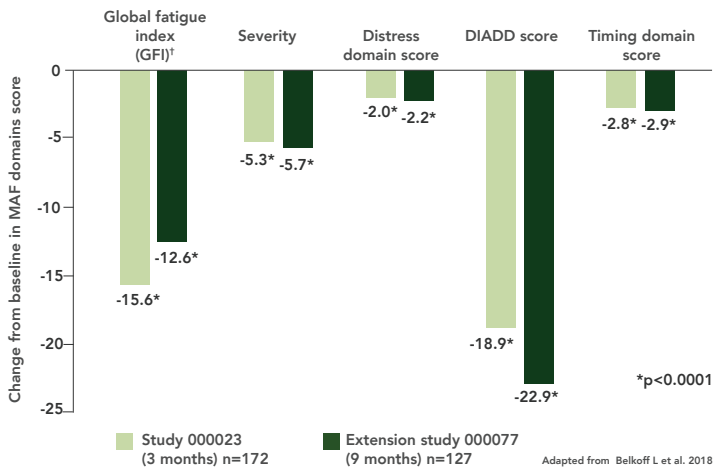
Significant improvement in mental and physical health at 3 and 9 months (p<0.0001) with TESTAVAN®[1]



Adapted from Belkoff L et al. 2018

FATIGUE

Significant improvement in fatigue scores at 3 and 9 months (p<0.0001) with TESTAVAN®[1]



Adapted from Belkoff L et al. 2018

TESTAVAN® provides rapid and sustained relief of symptoms[1,2]

TESTAVAN® DEMONSTRATES A WELL-TOLERATED SAFETY PROFILE, WITH LOW INCIDENCE OF ELEVATED PSA[1–4]

The safety of TESTAVAN® was evaluated in two phase 3, open-labelled, single-arm, multicentre studies*[1,2]

FAVOURABLE SKIN TOLERABILITY PROFILE

The most commonly reported adverse events in clinical trials were application site reactions (4%), lasting up to 9 months. The majority of these reactions were mild to moderate in severity[3]

LOW INCIDENCE OF ELEVATED PSA

TESTAVAN® showed that of 339 patients, only seven patients had PSA >0.1 nmol/L with a mean change from baseline of 0.24±0.67 ng/dL†[4]

LOW FREQUENCY OF HAEMATOCRIT EVENTS‡

TESTAVAN® showed that of 339 patients, only five had haematocrit >54%, 1.2% patients reported an event of increased haematocrit, and two withdrew from the study due to elevated haematocrit levels[4]

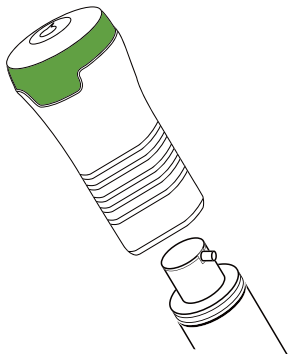
TESTAVAN® offers men with hypogonadism a favourable tolerability profile[3]

QOL Quality of life

References 1. Belkoff L et al. Andrologia 2018;50(1):e12801. 2. Cunningham G et al. Endocr Pract 2017;23(5):557–565.
3. TESTAVAN® SmPC The Simple Pharma Company. 4. Arver S et al. Andrology 2018;6(3):396–407.

TESTAVAN® HANDS-FREE APPLICATOR DELIVERS:

- Faster absorption and enhanced testosterone bioavailability compared with Testogel 1%*[1]
- Convenient hands-free application with a reduced risk of secondary transfer[2]
- Low application volume[1,2]



SIMPLE 3-DOSE TITRATION THAT CAN BE ADAPTED TO INDIVIDUAL PATIENT RESPONSE[1,2]

TESTAVAN® dosage should be titrated to maintain patient's serum testosterone level.*[2] Existence of clinical signs and symptoms related to testosterone deficiency should also be considered during dose titration.[2]

UP-TITRATE by 1 pump if serum testosterone level is <17.3 nmol/L (500 ng/dL)*

DOWN-TITRATE by 1 pump if serum testosterone level is >36.4 nmol/L (1050 ng/dL)*

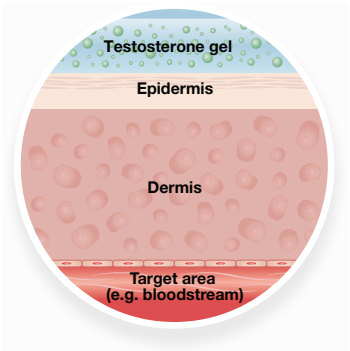
23 mg testosterone OD	**46 mg testosterone OD**	**69 mg testosterone OD**
1 PUMP ACTUATION Apply to one shoulder	2 PUMP ACTUATIONS Apply one pump to each shoulder	3 PUMP ACTUATIONS Apply to alternating shoulders

Recommended Starting Dose — Recommended Maximum Dose

*Patient's 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.
*No head-to-head comparative study available. Data presented cannot be directly compared and can only serve as indicative values.
OD, once daily.

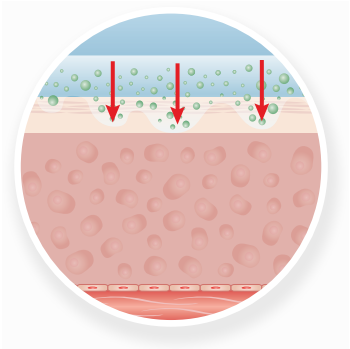
References 1. Olsson H et al. Clin Pharmacol Drug Dev 2014;3(5):358–364. 2. TESTAVAN® SmPC, 2019. Available at: www.androlabs.com/our-products 3. Arver S et al. Andrology 2018;6(3):396–40

UNIQUE TESTOSTERONE GEL PROVIDES RAPID DRUG ABSORPTION[1]



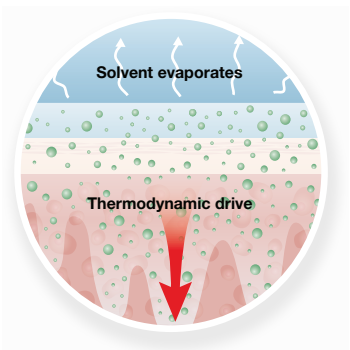
ENHANCES ABSORPTION

Maintains the drug in the molecular form for permeation into the skin/mucosa



RAPID PENETRATION

Increases fluidity of inter-cellular lipids, enabling movement through the skin



EXTENDS PENETRATION

Solvent evaporation **increases thermodynamic activity** and extends drug permeation

References: 1. Arver S et al. Andrology 2018;6(3):396–407.

THE EAU GUIDELINES RECOMMEND PATIENT-SPECIFIC ASSESSMENT AND SHORT-ACTING TRT AT THE BEGINNING[1]

Testosterone deficiency should be assessed in men with:

- **Sexual dysfunction**
- **Type 2 diabetes**
- **Metabolic syndrome**
- **Obesity**
- **Osteoporosis or low-trauma fractures**
- **HIV infection with sarcopenia**
- **Pituitary mass, following radiation involving the sellar region, and other diseases in the hypothalamic and sellar region**
- **Treatment with medications that cause suppression of testosterone levels**
- **Moderate to severe COPD**

The European Association of Urology (EAU) guidelines and the British Society for Sexual Medicine (BSSM) guidelines recommend testosterone deficiency is common, and in whom treatment may be indicated[1,2]

COPD, chronic obstructive pulmonary disease; **TRT**, testosterone replacement therapy.

COMMONLY REPORTED ADVERSE REACTIONS WITH **TESTAVAN®**[3]

MedDRA system organ class	Common (>1/100 to <1/10)
General disorders and administration site conditions	Application site reaction (including rash, erythema, pruritus, dermatitis, dryness and skin irritation)*
Investigations	Blood triglycerides increase/hypertriglyceridaemia, PSA increased, red blood cell count increased, haematocrit increased
Vascular disorders	Hypertension

TESTAVAN® drug-related adverse reactions reported during phase 2 and 3 clinical trials, with more than one case (n=379)[4,5]

Watch the TESTAVAN® application video by scanning this QR code

SCAN ME

*TESTAVAN® contains alcohol and frequent applications to the skin may cause irritation and dry skin[3]
* | PSA, prostate specific antigen.

References: 1. Dohle G et al. EAU Guidelines on Male Hypogonadism 2018. Available at: http://uroweb.org/guideline/male-hypogonadism. 2. Hackett G, Kirby M, Edwards D et al. BSSM Guidelines. J Sex Med 2017; 14: 1504–1523. 3. TESTAVAN® SmPC, 2019. Available at: www.andro-labs.com/our-products. 4. Cunningham G et al. Endocr Pract 2017;23(5):557–565. 5. Belkoff L et al. Andrologia 2018;50(1):e12801

PRESCRIBING INFORMATION Testavan® 20 mg/g Transdermal gel

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 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 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® 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.
Legal category: POM.
Marketing Authorisation Number: PL54460/0002
Marketing Authorisation Holder: The Simple Pharma Company UK Limited, Mappin House, 4 Winsley Street, London, W1W 8HF, UK.
Date of preparation of Prescribing Information: June 2022.

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
The Simple Pharma Company
email: pharmacovigilance@simplepharma.com

Please access Testavan® Summary of Product Characteristics via the link below
www.andro-labs.com/our-products

or scan the QR code

SCAN ME

Date of preparation: June 2022 PROMO_1582