
Testogel
(testosterone)
16.2 mg/g gel
TESTICULAR CANCER
SURVIVORS ARE AT
RISK OF DEVELOPING
TESTOSTERONE
DEFICIENCY.
Could your patients
be suffering?[1,2]
Testogel 16.2 mg/g is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.[3]
BESINS
HEALTHCARE
Innovating for Well-being

TESTICULAR CANCER AND ITS TREATMENT ARE PUTTING YOUR PATIENTS AT RISK OF DEVELOPING TESTOSTERONE DEFICIENCY.[1,2]

20%

Around 20% of **testicular cancer survivors** experience **testosterone deficiency.**[1]

40%

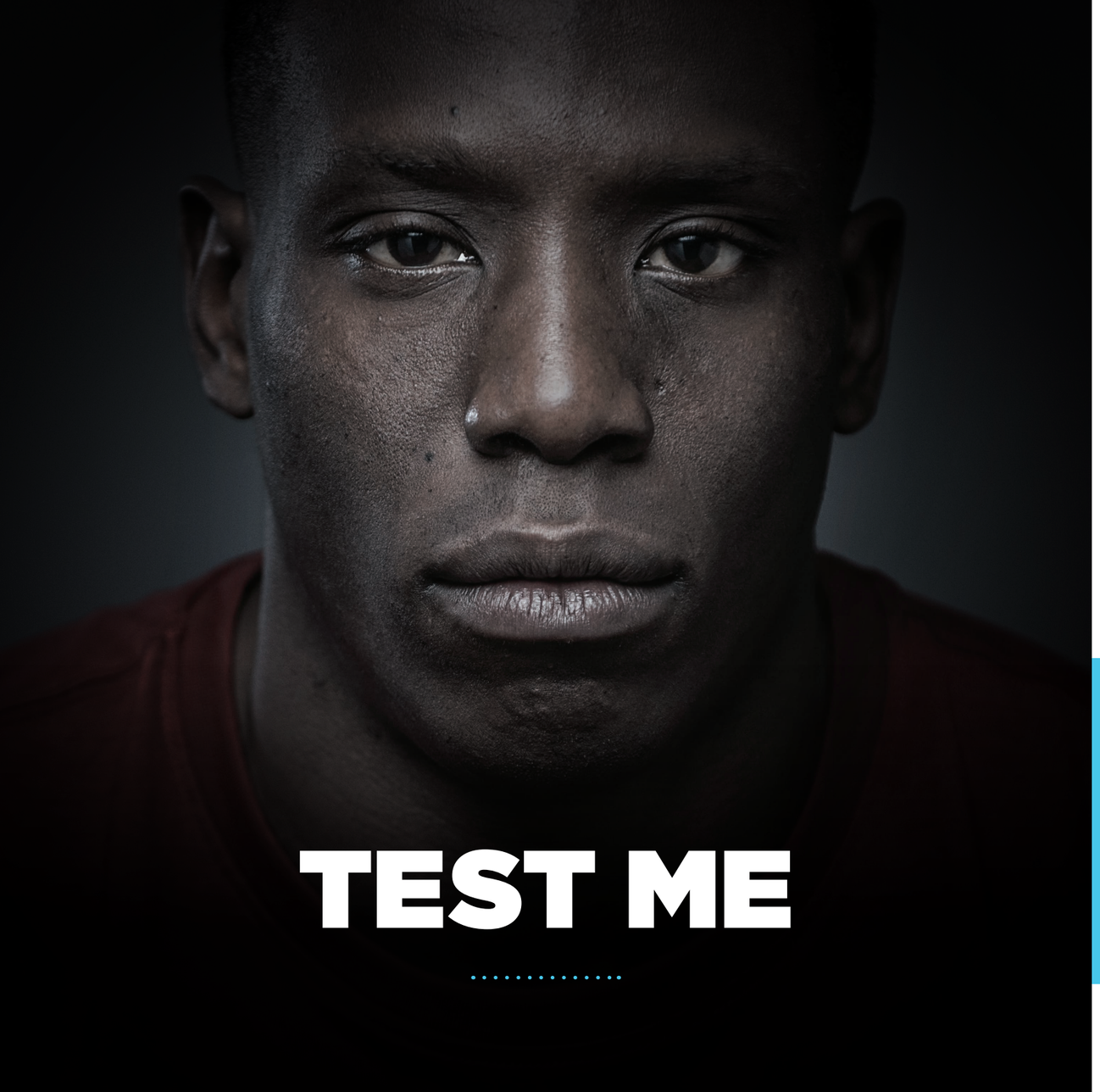
Almost 40% of **testicular cancer survivors** develop **testosterone deficiency** after receiving platinum-based chemotherapy.[2]

TESTOSTERONE DEFICIENCY COULD HAVE LONG-TERM CONSEQUENCES FOR TESTICULAR CANCER SURVIVORS.[4–10]

The effects of testosterone deficiency are not limited to erectile dysfunction and low libido; testicular cancer survivors who develop testosterone deficiency can suffer from **metabolic syndrome** and **poor cardiac health.**[1,2,4–8]

It is now thought that the main contributing factors in the development of **metabolic syndrome** in testicular cancer survivors are **testosterone deficiency** and **chemotherapy.**[9,10]

As long-term survival in testicular cancer remains high, effective follow-up monitoring should be a priority.[11,12]



TEST ME

HAVE ALL YOUR TESTICULAR CANCER SURVIVORS BEEN ROUTINELY SCREENED FOR SYMPTOMS OF TESTOSTERONE DEFICIENCY?

The European Society for Medical Oncology (ESMO) recommends monitoring of total testosterone, luteinizing hormone (LH) and follicle-stimulating hormone (FSH) in all patients post orchidectomy.[13]

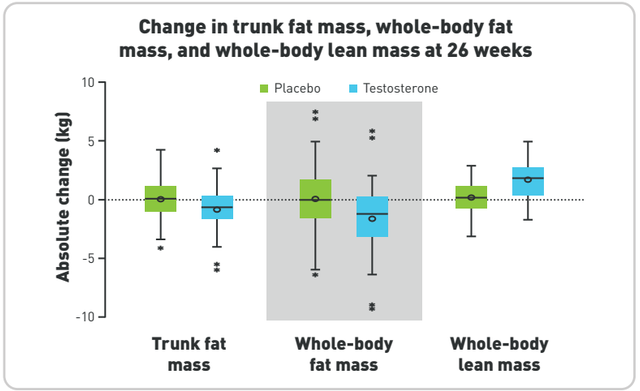
The **ADAM** questionnaire and **AMS** scale (available at testogelpump.co.uk) can help you catch symptoms which are not proactively mentioned by men during follow-up appointments.[4]

If symptoms are present, low serum testosterone levels can confirm a diagnosis.[4]

Encourage your patients to report symptoms during follow-up appointments, by providing education about potential long-term complications, such as testosterone deficiency.[14]

TESTOSTERONE THERAPY CAN REDUCE THE RISK OF LONG-TERM ADVERSE METABOLIC AND CARDIOVASCULAR IMPACT IN PATIENTS WITH TESTOSTERONE DEFICIENCY.[7,15–19*]

Obesity, diabetes, metabolic syndrome and cardiovascular disease are all closely related conditions associated with testosterone deficiency and can have negative long-term health impacts.[4,18.20]



In a 6-month double-blind randomised placebo-controlled trial of young male cancer survivors (TRYMS study), **testosterone therapy** was associated with **significant improvement in body composition** in testicular cancer survivors vs. placebo at 26 weeks.[15]

Significantly REDUCED TRUNK FAT MASS (-0.9kg p=0.073)

Significantly REDUCED WHOLE-BODY FAT MASS (-1.8kg p=0.016)

Significantly INCREASED LEAN BODY MASS (+1.5g p=0.001)

The active treatment in the above study was testosterone 2% gel (Kyowa Kirin).
**The studies include data on patients receiving a range of testosterone therapies including gels.*

HOW CAN TESTOGEL 16.2 MG/G GEL HELP YOUR TESTICULAR CANCER PATIENTS?

Restores testosterone levels to within the normal range

Normal testosterone levels* were achieved at day 182 in 82.2% (139/169) of hypogonadal men treated with an optimised dose, in a randomised placebo-controlled trial involving 274 patients.[3,21]

Simple, convenient, once-daily application

The recommended dose is two actuations. The pump enables flexible titration as required.†[3]

Well tolerated

Well tolerated: only 1-10% of incidence of skin reactions.[3] Please refer to the prescribing information for further details regarding undesirable effects.

Online support

Besins Healthcare offer a comprehensive Patient Support Program that aims to instil confident, regular use of the treatment, supporting patient compliance and better clinical outcomes.

*In this study, a normal range was defined as a serum total testosterone average concentration of 300-1000 ng/dL (10.4–34.7 nmol/L).

†Testosterone levels should be monitored at baseline and at regular intervals during the above treatment. Clinicians should adjust the dosage depending on the clinical or laboratory response in individual patients.

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 1.25 g of gel containing 20.25 mg of testosterone. **Indication:** Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Dosage and administration:** Cutaneous use. The recommended dose is two pump actuations of gel (i.e. 40.5 mg of testosterone) applied once daily. The daily dose should not exceed four pump actuations (81 mg testosterone) per day. Adjustment of dosage should be achieved by increments of one pump actuation, 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. Allow to dry for at least 3–5 minutes before dressing. **Contraindications:** Cases of known or suspected cancer of the prostate or breast, known hypersensitivity to testosterone or to any other constituent of the gel. **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, in patients receiving long-term androgen treatment the following laboratory parameters should be checked regularly: haemoglobin, haematocrit (to detect polycythaemia), liver function tests, 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 pre-clinical prostate cancer and benign prostate hyperplasia. Testogel should be used with caution in cancer patients at risk of hypercalcemia and associated hypercalciuria due to bone metastases; regular monitoring of blood calcium levels is recommended in these patients. Testogel may cause oedema with or without congestive cardiac failure in patients suffering from severe cardiac, hepatic or renal insufficiency or ischaemic heart disease. If this occurs, treatment must be stopped immediately. 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. There are published reports of increased risk of sleep apnoea in hypogonadal subjects treated with testosterone esters, especially in those with risk factors such as obesity and chronic respiratory disease. Spermatogenesis may be suppressed leading to adverse effects on semen parameters. Gynecomastia 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. Do not apply to the genital areas as the high alcohol content may cause local irritation. 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. For further details refer to the SPC. **Interactions:** May increase the activity of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. May cause changes in insulin sensitivity, glucose intolerance, glycaemic control, blood glucose and glycosylated haemoglobin levels. **Pregnancy and lactation:** Pregnant women must avoid any contact with Testogel application sites. This product may have adverse virilising effects on the foetus. **Undesirable effects:** Local skin reactions include: acne, alopecia, dry skin, skin lesions, contact dermatitis, hair colour changes, rash, sweating, hypertrichosis, 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 and increased red blood cell count. 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. Other known adverse drug reactions: testis disorder, headache, dizziness, paraesthesia, vasodilation (hot flushes), deep vein thrombosis, dyspnoea, polycythaemia, anaemia, musculoskeletal pain, prostate enlargement, oligospermia, benign prostatic hyperplasia, impaired urination, anxiety, depression, aggression, insomnia, nausea, asthenia, oedema, malaise and weight increase. In case of severe application site reactions, treatment should be reviewed and discontinued if necessary. **NHS Price:** £31.11 per 88g pump pack. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0007. **Marketing Authorisation Holder:** Besins Healthcare, Avenue Louise, 287, Brussels, Belgium. **Date of preparation of Prescribing Information:** 06 September 2019 TES/2019/063.

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

References:

1. Haugnes HS, *et al. J Clin Oncol.* 2010;28(30):4649-4657. **2.** Abu Zaid M, *et al. J Natl Compr Cancer Netw JNCCN.* 2019;17(5):459-468. **3.** Testogel 16.2mg/g gel – Summary of Product Characteristics (SmPC) – (emc). **4.** Lunenfeld B, *et al. Aging Male.* 2015;18(1):5-15. **5.** Khera M, *et al. J Sex Med.* 2016;13(12):1787-1804. **6.** Zarotsky V, *et al. Andrology.* 2014;2(6):819-834. **7.** Sharma R, *et al. Eur Heart J.* 2015;36(40):2706-2715. **8.** Zeller T, *et al. Eur J Prev Cardiol.* 2018;25(11):1133-1139. **9.** IJpma I, *et al. Appetite.* 2016;105:392-399. **10.** Westerink NL, *et al. Crit Rev Oncol Hematol.* 2016;108:128-136. **11.** Cancer Research UK. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/testicular-cancer/ (accessed December 2020). **12.** Steggink LC, *et al. Andrology.* 2019;7(4):441-448. **13.** Oldenburg J, *et al. Ann Oncol Off J Eur Soc Med Oncol.* 2013;24 Suppl 6:vi125-132. **14.** British Society for Sexual Medicine. http://www.bssm.org.uk/wp content/uploads/2020/01/BSSMconsensus- on-Testicular-cancer-final-2020.pdf (accessed February 2021). **15.** Walsh JS, *et al. PLoS Med.* 2019;16(11):e1002960. **16.** Oni OA, *et al. Am J Cardiol.* 2019;124(8):1171-1178. **17.** Corona G, *et al. J Sex Med.* 2018;15(6):820-838. **18.** Hackett G, *et al. Int J Clin Pract.* 2017;71(3-4). **19.** Hackett G, *et al. Int J Clin Pract.* 2016;70(3):244-253. **20.** Grundy SM. *J Clin Endocrinol Metab.* 2004;89(6):2595–2600. **21.** Kaufman JM, *et al. J Sex Med.* 2012;9(4):1149–1161.

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