
Testogel
(testosterone)
16.2 mg/g gel
TESTOSTERONE DEFICIENCY
CAN BE THE CAUSE OF
UNEXPLAINED ANAEMIA.
Could it be the
reason behind your
patient's symptoms?[1–3]
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.[4]
BESINS
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TESTOSTERONE DEFICIENCY MAY BE CAUSING YOUR PATIENTS' UNEXPLAINED ANAEMIA.[1–3]

17%

Anaemia affects around 17% of adults ≥65 years old, equal to **15 million people in Europe.**[5]

20-44%

In approximately 20–44% of elderly adults with anaemia, **no recognised cause can be found.**[6]

35%

Primary hypogonadism was identified in over **35% of unexplained anaemia cases** in a UK hospital setting.[2]

The link between **testosterone** and **erythropoiesis** has been established for decades, and testosterone could play a key role in the stimulation and regulation of the hematopoietic system.[1,3]

This association means **low levels of testosterone** can have a detrimental impact on the production of red blood cells and **may be the cause of unexplained anemia in your male patients.**[1–3]

Have you considered testosterone deficiency as a possible cause of unexplained anaemia in your male patients?

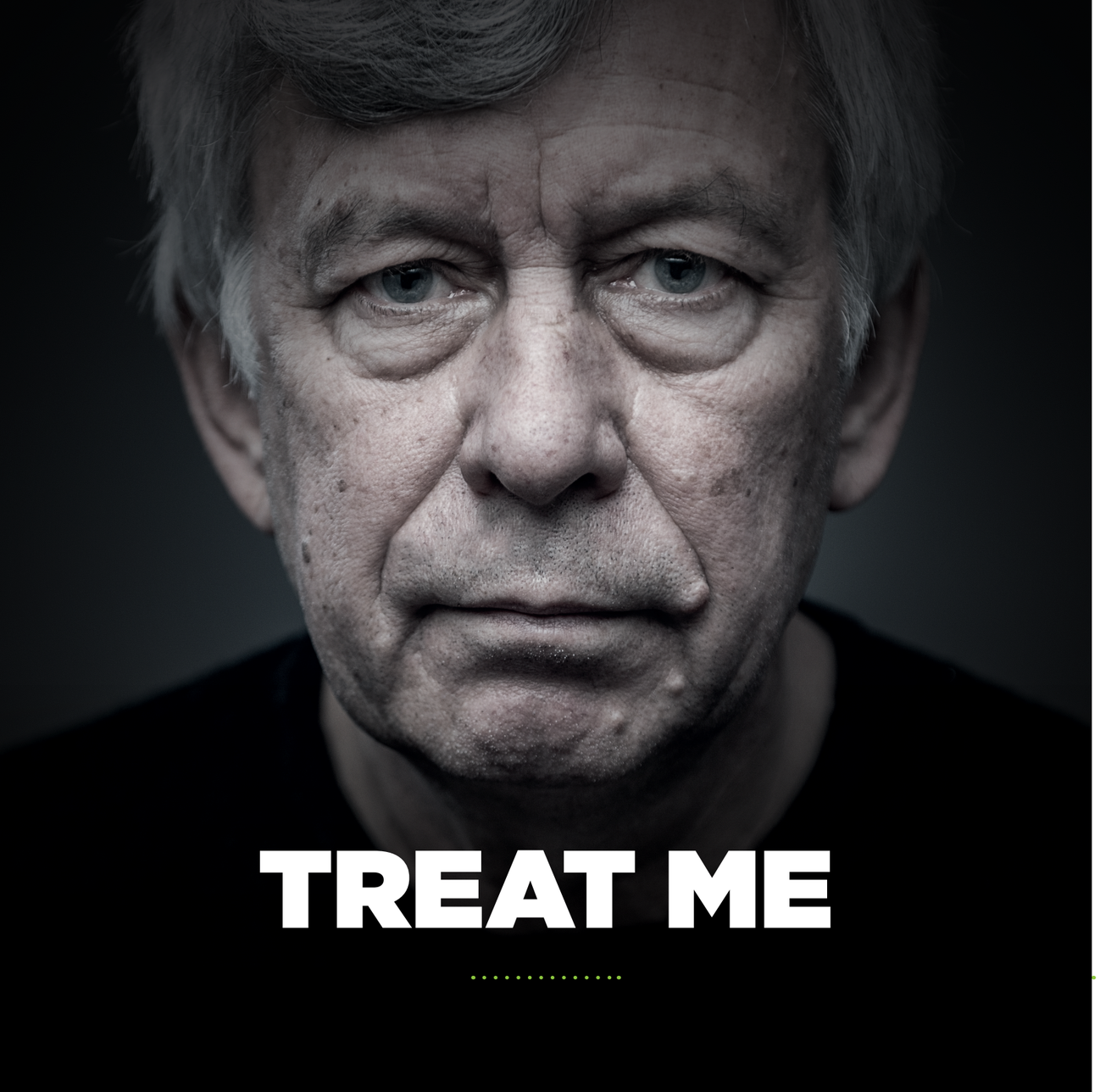
SCREEN ME

CONSIDER SCREENING FOR HYPOGONADISM IN MEN WITH A HISTORY OF ANAEMIA.[7]

Screening for hypogonadism should form part of a standard anaemia work-up in men by all physicians, not just endocrinologists.[7]

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.[8]

If symptoms are present, low serum testosterone levels can confirm a diagnosis.[9,10]



TESTOSTERONE THERAPY CAN RESOLVE UNEXPLAINED ANAEMIA IN MEN WITH TESTOSTERONE DEFICIENCY.[11]

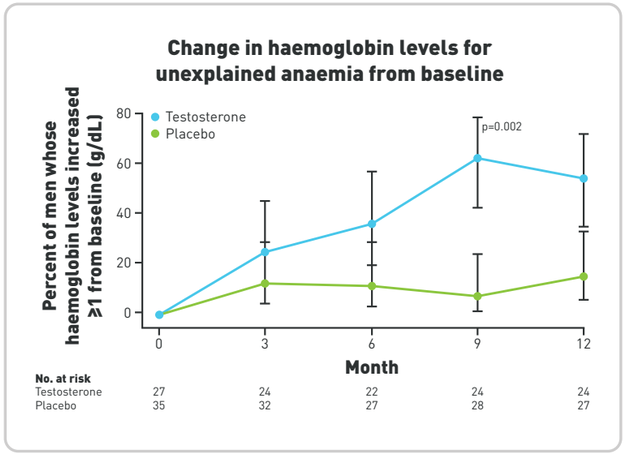
In a 12-month, **double-blind, placebo-controlled**, multicentre study of **elderly men** with **TD and anaemia**:[11]

58.3%

At month 12, 58.3% of testosterone deficient men treated with testosterone therapy were no longer anaemic vs. 22.2% of men receiving placebo.[11]

54%

Testosterone therapy increased haemoglobin levels by ≥1 g/dL above baseline in 54% of men with TD and unexplained anaemia vs. 15% in men receiving placebo.[11]



The Endocrine Society's Clinical Practice Guideline recommends

measuring testosterone and offering testosterone replacement therapy on an individualised basis for men aged >65 with symptoms or conditions suggestive of testosterone deficiency (including unexplained anaemia), after discussions of the potential risks and benefits.[9]

TESTOSTERONE DEFICIENCY CAN HAVE LIFE-CHANGING CONSEQUENCES.

Symptoms of testosterone deficiency are wide-ranging and can include:[8,12–14]

- **Metabolic syndrome**
- **Poor cardiac health**
- **Increased risk of type 2 diabetes**
- **Fatigue**

Testogel 16.2 mg/g gel may help raise haemoglobin levels and resolve unexplained anaemia in your male patients with testosterone deficiency.[11]

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.[4,15]

Simple, convenient, once-daily application

The recommended dose is two actuations. The pump enables flexible titration as required.†[4]

Well tolerated

Well tolerated: only 1-10% of incidence of skin reactions.[4] 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 sub-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 hair, 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.

TO BE COMPLETED WITH NEW PI

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. Al-Sharefi A, *et al. Front Endocrinol.* 2019;10. **2.** Al-Sharefi A, *et al. Clin Endocrinol (Oxf).* 2018;89(4):527-529. **3.** Shahani S, *et al. J Endocrinol Invest.* 2009;32(8):704-716. **4.** Testogel 16.2mg/g gel - Summary of Product Characteristics (SmPC) - (emc). **5.** Stauder R, *et al. Haematologica.* 2014;99(7):1127-1130. **6.** Merchant AA, *Br J Haematol.* 2012;156(2):173-185. **7.** Al-Sharefi A, *et al. Br J Gen Pract.* 2020;70(696):364-365. **8.** Lunenfeld B, *et al. Aging Male.* 2015;18(1):5-15. **9.** Bhasin S, *et al. J Clin Endocrinol Metab.* 2018;103(5):1715-1744. **10.** Mulhall JP, *et al. J Urol.* 2018;200(2):423-432. **11.** Roy CN, *et al. JAMA Intern Med.* 2017;177(4):480-490. **12.** Khera M, *et al. J Sex Med.* 2016;13(12):1787-1804. **13.** Zarotsky V, *et al. Andrology.* 2014;2(6):819-834. **14.** Zeller T, *et al. Eur J Prev Cardiol.* 2018;25(11):1133-1139. **15.** Kaufman JM, *et al. J Sex Med.* 2012;9(4):1149-1161.

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