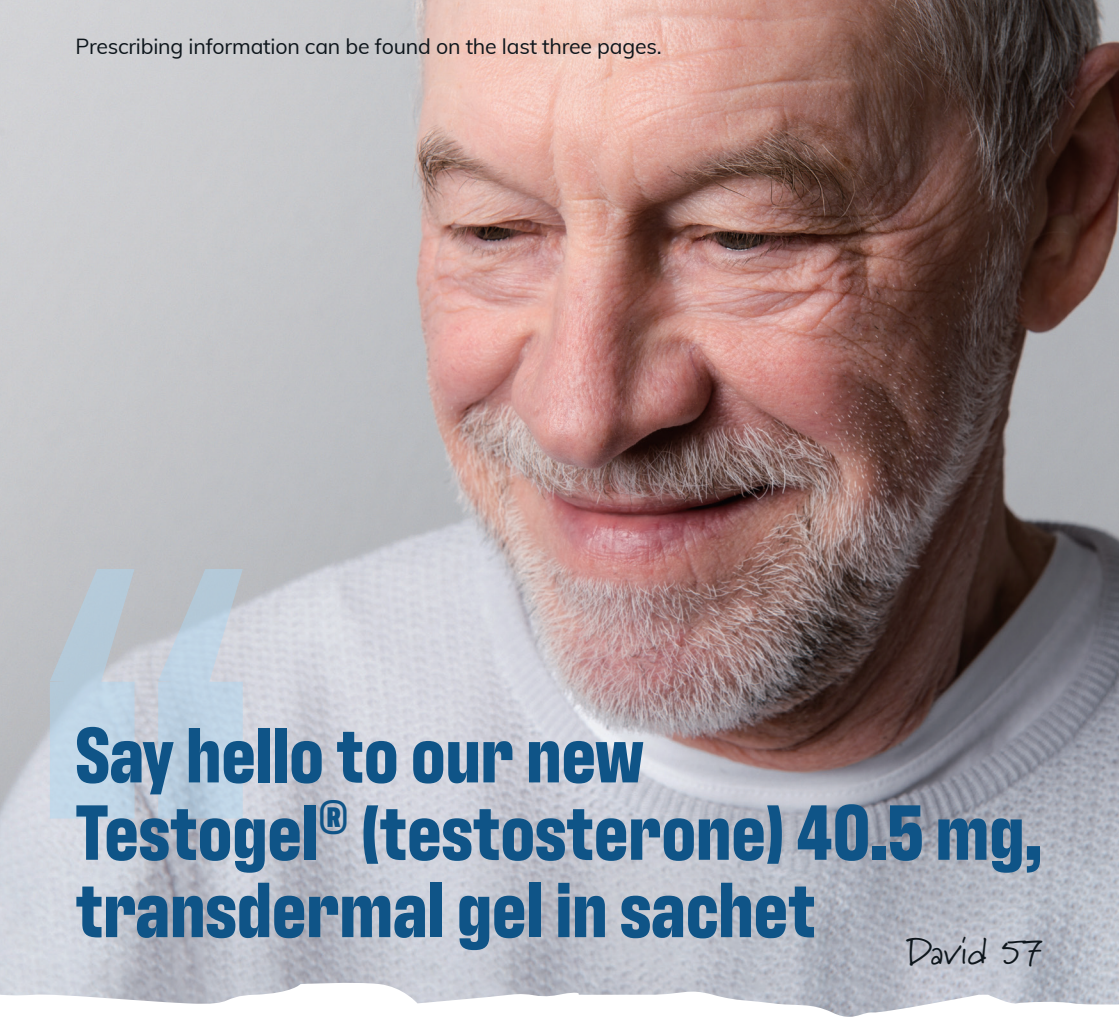
Prescribing information can be found on the last three pages.



Say hello to our new Testogel® (testosterone) 40.5 mg, transdermal gel in sachet

David 57

Information for prescribers about initiating and moving patients to the new Testogel® 40.5 mg, transdermal gel in sachet from Testogel® 50 mg, transdermal gel in sachet.

Testogel® 40.5 mg, transdermal gel in sachet is indicated in adults as testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and two separate blood testosterone measurements. Due to interlaboratory variability, all measurements of testosterone should be carried out by the same laboratory.[1]

This leaflet is provided for HCPs in the UK by Besins Healthcare (UK) Ltd.

BESINS HEALTHCARE
Innovating for Well-being

Testogel (testosterone)

Introducing the new Testogel® 40.5 mg, transdermal gel in sachet

The Testogel® range is changing.
We are harmonising our products by launching a new 40.5 mg, transdermal gel in sachet to replace the 50 mg sachet, giving patients the flexibility to easily switch between the pump and sachet.

Testogel® 40.5 mg, transdermal gel in sachet contains the same effective 16.2 mg/g gel found in the Testogel® pump, and will be available at the same price. Testogel® 16.2 mg/g gel is trusted by HCPs and patients alike, as the most prescribed testosterone gel in the UK.[2]

Testogel® 40.5 mg is a more concentrated gel than Testogel® 50 mg.
A lower volume of Testogel® 40.5 mg gel than Testogel® 50 mg gel is required to apply the recommended dose, making application more convenient for patients.

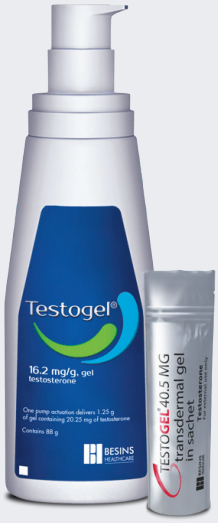
Product	Recommended dose of formulation per day	Amount of gel
Testogel® 50 mg, transdermal gel in sachet	**50 mg testosterone**	**5 g**
Testogel® 40.5 mg, transdermal gel in sachet	**40.5 mg testosterone**	**2.5 g**

Testogel® 40.5mg, transdermal gel in sachet restores testosterone 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]

2017 BSSM Guidelines recommend a target therapeutic range of 15–30 nmol/L.[5]
The Testogel® 40.5 mg, transdermal gel in sachet will be available from the 14th February 2022. The Testogel® 50 mg sachet will be available until the end of March 2022 to allow a smooth transition to the 40.5 mg, transdermal gel in sachet.

This leaflet will provide you with important information to support your patients as they transition to Testogel® 40.5 mg, transdermal gel in sachet.

THE TESTOGEL® 40.5 MG, TRANSDERMAL GEL IN SACHET AND TESTOGEL® 16.2 MG/G PUMP ARE INTERCHANGEABLE, GIVING PATIENTS THE FLEXIBILITY TO EASILY SWITCH BETWEEN PRODUCTS.[1,7]



Dosing for Testogel® 40.5 mg, transdermal gel in sachet

You and your patients now have a choice

Testogel® 40.5 mg, transdermal gel in sachet is the same formulation of Testogel® used in the 16.2 mg/g gel Testogel® pump - giving you, and your patients switching from the 50 mg sachet, the option to stay on a sachet or use the pump.

THE RECOMMENDED DAILY DOSE OF TESTOGEL® 40.5 MG IS 1 X SACHET, WHICH IS EQUIVALENT TO 2 X TESTOGEL® 16.2 MG/G GEL PUMP ACTUATIONS.[1,7]

Patients should be monitored regularly to ensure they are on the correct dosage. The daily dose should be adjusted depending on the clinical or laboratory response in individual patients, not exceeding 81 mg of testosterone per day, as recommended in the Summary of Product Characteristics.[1,7]

PRESCRIBE TESTOGEL® BY BRAND NAME TO AVOID CHANGE AT THE PHARMACY AND TO BENEFIT FROM OUR PATIENT SUPPORT PROGRAM, WHICH AIMS TO INSTIL CONFIDENT, REGULAR USE OF TREATMENT, SUPPORTING PATIENT COMPLIANCE AND BETTER CLINICAL OUTCOMES.

Simple, convenient, well-tolerated[1]

How to apply Testogel® 40.5 mg, transdermal gel in sachet[1]

	Apply a thin layer of Testogel® 40.5 mg, transdermal gel in sachet onto clean, healthy skin over the upper arms and shoulders, once-a-day, washing hands after application. **Please note:** patients could apply Testogel® 50 mg to their abdomen, which is not recommended for Testogel® 40.5 mg, transdermal gel in sachet. Testogel® 40.5 mg should NOT be applied to the abdomen or genitals.[1,2]
	No application site rotation or dose applicator is required.
	Allow the gel to dry for at least 3–5 minutes before dressing. Testogel® 40.5 mg, transdermal gel in sachet is flammable until dry.
	Recommended period between application and showering/bathing is 1 hour. Testosterone can be transferred by skin-to-skin contact and result in adverse events. The application site should be washed thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.

TESTOGEL® 40.5 MG, TRANSDERMAL GEL IN SACHET IS WELL-TOLERATED[1]

The most frequently observed adverse drug reactions at the recommended dosage of gel per day were skin reactions: reaction at the application site, erythema, acne, and dry skin.[1]

MedDRA System Organ Class	Common adverse reactions (>1/100; <1/10)
Psychiatric disorders	Mood disorders
Nervous system disorders	Dizziness, paraesthesia, amnesia, hyperaesthesia
Vascular disorders	Hypertension
Gastro-intestinal disorders	Diarrhoea
Skin and subcutaneous tissue disorders	Alopecia, urticaria
Reproductive system and breast disorders	Gynaecomastia (which may be persistent, is a common finding in patients treated for hypogonadism), mastodynia, prostatic disorders
General disorders and administration site conditions	Headache
Investigations	Changes in laboratory tests (polycythaemia, lipids). ematocrit increased, red blood count increased, haemoglobin increased

Testogel® 40.5 mg, transdermal gel in sachet is contraindicated in cases of known or suspected prostatic cancer or breast carcinoma and in cases of known hypersensitivity to the active substance or any of the excipients.[1]

Please refer to the Summary of Product Characteristics for further details regarding special warnings, precautions for use and a full list of excipients.[1]

FAQs—what questions might my patients ask?

How does Testogel® 40.5 mg, transdermal gel in sachet fit into the Testogel® range? Testogel® 40.5 mg, transdermal gel in sachet has been introduced to replace Testogel® 50 mg, transdermal gel in sachet, harmonising the Testogel® range. Testogel® 40.5 mg, transdermal gel in a sachet returns testosterone levels within the normal range with a smaller, more concentrated volume of gel. It is just as effective as the 16.2 mg/g gel found in the Testogel® pump, giving patients the flexibility to easily switch between the pump and sachet.

Please note, if patients are planning to interchange between pump and sachet, they should be made aware that the dosing differs.

THE RECOMMENDED DAILY DOSE OF TESTOGEL® 40.5 MG IS 1 X SACHET, WHICH IS EQUIVALENT TO 2 X TESTOGEL® 16.2 MG/G GEL PUMP ACTUATIONS.[1]

What are the application sites for Testogel® 40.5 mg, transdermal gel in sachet?
Testogel® 40.5 mg, transdermal gel in sachet should be applied to clean, dry, intact skin of the upper arms and shoulders. Do not apply Testogel® 40.5 mg, transdermal gel in sachet to any other parts of the body.[1]

For more information on applying Testogel® 40.5 mg, transdermal gel in sachet consult the Method of administration section of the Testogel® 40.5 mg, transdermal gel in sachet SmPC.

How do I prescribe Testogel® 40.5 mg, transdermal gel in sachet?
On prescribing systems, the name of the product will appear as brand and as a non-proprietary name.

They may be shown as follows:[8]
Brand description: Testogel® 40.5 mg, transdermal gel in sachet Non–proprietary description: Testosterone 40.5 mg

How do I transition from Testogel® 50 mg to Testogel® 40.5 mg, transdermal gel in sachet?
The Testogel® 40.5 mg, transdermal gel in sachet is available from the 14th February 2022. The Testogel® 50 mg sachet will be available until the end of March 2022 to allow a smooth transition to the 40.5 mg, transdermal gel in sachet.

The recommended starting dose for both Testogel® 50 mg and Testogel® 40.5 mg, transdermal gel in sachet is one sachet.

There are no comparative dosing studies that advise on how patients can be switched from one formulation of Testogel® to the other. The guidance in the individual products' Summary of Product Characteristics should be followed when starting and titrating the dose of a particular Testogel® formulation.[1,5]

Are there different side effects compared to the 50 mg sachet?
The side effect profiles are very similar, but not identical. Post-marketing experience has identified prostate abnormalities as an uncommon adverse event (≥1/1,000 to <1/100) for Testogel® 40.5 mg.[1] Otherwise, the safety profiles of each product are the same.[1,3]

If I had a patient on 2 x 50mg sachets (equalling 100mg of testosterone daily), how should I transition them to the 40.5mg sachet?

If your patient was administering 2 x 50 mg sachets per day, we recommend prescribing them 2 x 40.5 mg sachets per day instead. We strongly recommend routinely monitoring your patients following initiation on the 40.5 mg sachets until clinically and biochemically stable to ensure they are on the correct dosage. Prescribing of half sachets is possible and instructions can be found in the SmPC. Please note that the maximum daily dose of Testogel 40.5mg sachets is 81mg (2 sachets).

FOR MORE INFORMATION AND SUPPORT ON HOW TO AID THE INITIATION OR TRANSITION OF PATIENTS TO TESTOGEL® 40.5 MG OR TESTOGEL® 16.2 MG/G GEL, PLEASE VISIT THE TESTOGEL® WEBSITE AT WWW.TESTOGEL.CO.UK

Testogel® 40.5 mg sachet PI

Prescribing Information
Testogel® (testosterone) 40.5 mg,
transdermal gel in sachet
For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: 2.5 g sachets containing 40.5 mg of testosterone. 1.81g alcohol (ethanol) in each sachet of 2.5 g. **Indication:** In adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Posology and method of administration:** Adult and elderly men. Each sachet provides a dose of 2.5 g of gel (i.e. 40.5 mg of testosterone). The entire contents of one sachet should be applied once daily at about the same time, preferably in the morning. The daily dose should be adjusted up or down depending on the clinical or laboratory response in individual patients, not exceeding 81 mg of testosterone per day (2 sachets i.e. 5 g of gel). The adjustment of posology should be achieved byapproximately 1.25 g of gel (half sachet) steps. *Transdermal* use. The gel should be administered by the patient himself, onto clean, dry, healthy skin over right and left upper arms and shoulders. Allow drying for at least 3–5 minutes before dressing. Wash hands with soap and water after each application. Do not apply to the genital areas as the high alcohol content may cause local irritation. **Contraindications:** cases of known or suspected prostatic cancer or breast carcinoma, known hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions for use:**Testosterone insufficiency should be clearlydemonstrated by clinical features and confirmed by 2 separate blood testosterone measurements.Testosterone level should be monitored at baseline and at regular intervals during treatment. In patients receiving long-term androgen treatment the following laboratory parameters should be checked regularly:haemoglobin, haematocrit (to detect polycythaemia), liver function tests and lipid profile. 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 prostatic cancer. Testogel should be used with caution in cancer patients at risk of hypercalcemia and associated hypercalciuria due to bone metastases;regular monitoring of serum calcium concentrations is recommended in these patients. 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 such case, treatment must be stopped immediately. 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 or risk factors for venous thromboembolism. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen expsure requiring dosage adjustment. Testogel should be used with caution in patients with epilepsy and migraine as these conditions may be aggravated. In case of severe application site reactions, treatment should be reviewed and discontinued if necessary. 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. With large doses of exogenous androgens, spermatogenesis may be suppressed which could possibly lead to adverse effects on semen parameters including sperm count. Testogel is not indicated for use in women or in children under 18 years of age. For further details refer to the SPC. **Interactions:** Increased effect of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. Testogel may affect results of laboratory tests of thyroid function. In diabetic patients, the dose of antidiabetic medications may need reduction. **Pregnancy and lactation:** Pregnant women must avoid any contact with Testogel application sites. This product may have adverse virilising effects on the foetus. Spermatogenesis may be reversibly suppressed with this medicine. **Undesirable effects:** The most frequently observed adverse drug reactions at the recommended dosage of gel per day were skin reactions: reaction at the application site, erythema, acne, dry skin. Common; mood disorders, diziness, paraesthesia, amnesia, hyperaesthesia, hypertension, diarrhoea, alopecia, urticaria, gynaecomastia, mastodynia, prostatic disorders, headache, changes in laboratory tests (polycythaemia, lipids), haematocrit increased, red blood count increased, haemoglobin increased. Serious adverse reactions; hepatic neoplasm, prostate cancer, urinary obstructions, priapism. Prescribers should consult the SmPC in relation to other adverse reactions.**NHS Price:** 31.11 per 30 sachets. **Legal category:** POM. **Marketing Authorisation Number:** PL42714/0005. **Marketing Authorisation Holder:** Besins Healthcare (UK) Ltd, Lion Court, 25 Procter Street, Holborn, London, WC1V 6NY, UK. **Date of preparation of Prescribing Information:** January 2022. TES/2022/006

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 Email: pharmacovigilance@besins-healthcare.com

Testogel® 50 mg sachet PI

Prescribing Information
Testogel® (testosterone) 50 mg,
transdermal gel in sachet
For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: One sachet of 5 g contains 50 mg of testosterone. **Excipients with known effect:** Ethanol **Indication:** Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Posology and method of administration:** Adult and elderly men: the recommended dose is 5 g of gel (i.e. 50 mg of testosterone) applied once daily at about the same time, preferably in the morning. The daily dose should be adjusted by the doctor depending on the clinical or laboratory response in individual patients, not exceeding 10 g of gel per day. The adjustment of posology should be achieved by 2.5 g of gel steps Transdermal use. The gel should be administered by the patient himself, onto clean, dry, healthy skin over both shoulders, or both arms, or abdomen. Allow drying for at least 3–5 minutes before dressing. Wash hands with soap and water after each application. Do not apply to the genital areas as the high alcohol content may cause local irritation. **Contraindications:** Cases of known or suspected prostatic cancer or breast carcinoma, known hypersensitivity to the active substance or any of the excipients. **Warnings and precautions for use:** Testosterone insufficiency should be clearly demonstrated by clinical features and confirmed by 2 separate blood testosterone measurements. Testosterone level should be monitored at basline 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. 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 prostatic cancer. Testogel should be used with caution in cancer patients at risk of hypercalcemia and associated hypercalciuria due to bone metastases; regular monitoring of serum calcium concentrations is recommended in these patients. Testogel may cause severe complications characterised by 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. 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 or risk factors for venous thromboembolism. 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. In case of severe application site reactions, treatment should be reviewed and discontinued if necessary. 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. For further details refer to the SPC. **Interactions:** Increased effect of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. Testogel may affect results of laboratory tests of thyroid function. In diabetic patients, the dose of antidiabetic medications may need redution. **Pregnancy and lactation:** Pregnant women must avoid any contact with Testogel application sites. This product may have adverse virilising effects on the foetus. Spermatogenesis may be reversibly suppressed with this medicine. **Undesirable effects:** The most frequently observed adverse drug reactions at the recommended dosage of gel per day were skin reactions: reaction at the application site, erythema, acne, dry skin. Common; mood disorders, dizziness, paraesthesia, amnesia, hyperaesthesia, hypertension, diarrhoea, alopecia, urticaria, gynaecomastia, mastodynia, prostatic disorders, headache, changes in laboratory tests (polycythaemia, lipids), haematocrit increased, red blood count increased, haemoglobin increased. Serious adverse reactions; hepatic neoplasm, prostate cancer, urinary obstructions, priapism. Prescribers should consult the SmPC in relation to other adverse reactions. **NHS Price:** 31.11 per 30 sachets. **Legal category:** POM. **Marketing Authorisation Number:** PL 42714/0002. **Marketing Authorisation Holder:** Besins Healthcare (UK) Limited, Lion Court, 25 Procter St, Holborn, London, WC1V 6NY United Kingdom. **Date of preparation of Prescribing Information:** January 2022. TES/2022/007

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 Email: pharmacovigilance@besins-healthcare.com

Testogel 16.2 mg pump PI

BESINS HEALTHCARE
Innovating for Well-being

Testogel (testosterone)

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. 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 deficiency 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 and 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 hypercalcaemia 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 or risk factors for venous thromboembolism (VTE), as there have been post-marketing reports of thrombotic events in these patients during testosterone therapy. In thrombophilic patients, VTE cases have been reported even under anticoagulation treatment, therefore continuing testosterone therapy after first thrombotic event should be carefully evaluated. In case of treatment continuation, further measures should be taken to minimise the individual VTE risk. Spermatogenesis may be suppressed leading to adverse effects on semen parameters. Gynaecomastia 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 is flammable until dry. 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 THE FULL LIST OF WARNINGS AND PRECAUTIONS PLEASE CONSULT SECTION 4.4 OF THE FULL SPC. **Interactions:** May increase the activity of oral anticoagulants. Concomitant administration of testosterone and ACTH or corticosteroids may increase the risk of developing oedema. Testogel 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 adverse reaction identified during post-approval use of Testogel: testis disorder, headache, dizziness, paraesthesia, vasodilation (hot flushes), deep vein thrombosis, dyspnoea, polycythaemia, anaemia, musculoskeletal pain, gynaecomastia, testis disorder, prostate enlargement, oligospermia, benign prostate 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 88 g 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:** February 2021 TES/2021/016

Adverse events should be reported
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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 Email: pharmacovigilance@besins-healthcare.com

References: **1.** Testogel 40.5 mg, transdermal gel in a sachet Summary of Product Characteristics - https://www.medicines.org.uk/emc/product/13255/smpc. Accessed March 2022. **2.** Data on file TES/2022/005. **3.** Testogel 50 mg, transdermal gel in sachet – Summary of Product Characteristics (SmPC) – https://www.medicines.org.uk/emc/product/6808/smpc. Accessed March 2022. **4.** Kaufman JM, Miller MG, Garwin JL, et al. Efficacy and safety study of 1.62% testosterone gel for the treatment of hypogonadal men. J Sex Med. 2011;8(7):2079–2089 **5.** Hackett G, Kirby M, Edwards D, et al. British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice. J Sex Med. 2017;14:1504–1523. **6.** Swerdloff RS, Wang C, Cunningham, et al. Long-term pharmacokinetics of transdermal testosterone gel in hypogonadal men. J Clin Endocrinol Metab. 2000;85(12):4500–4510. **7.** Testogel 16.2 mg/g gel – Summary of Product Characteristics (SmPC) – https://www.medicines.org.uk/emc/product/8919/smpc. Accessed March 2022. **8.** National Institute for Health and Care Excellence (NICE). Testosterone, Gel. Available at: https://bnf.nice.org.uk/medicinal-forms/testosterone.html. Accessed March 2022.

TES/2022/003 **Date of preparation:** March 2022.