New Testogel® 16.2 mg/g gel (testosterone)

From Besins healthcare, the company that brought you the number one selling testosterone replacement therapy worldwide[1]

BESINS HEALTHCARE
Innovating for Well-being

Testogel
16.2 mg/g gel
(testosterone)

Put back the testosterone, complete the man

Prescribing information can be found on back.

Introducing new Testogel 16.2 mg/g gel: A new formulation in a new pump

Testogel now comes in an easy-to-use pump with flexible dosing enabling the doctor to tailor the dose[2]

New Testogel 16.2 mg/g gel:

> Returns testosterone level to within the normal range with a smaller, more concentrated volume of gel compared to Testogel 50 mg, gel in sachet (10mg/g)[3]

> Simple to initiate

> Well tolerated[3]

> NHS Price: £31.11 per pack (equivalent to Testogel 50 mg gel)[4]

Comparative dosing of Testogel 50 mg gel and Testogel 16.2 mg/g gel

It's simple to dispense the prescribed dose of Testogel 16.2 mg/g gel[2,5]

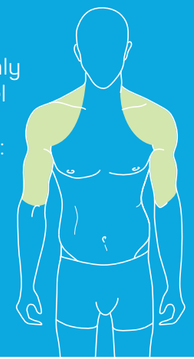
Daily dose of Testogel 50 mg gel	No. sachets of Testogel 50 mg gel (once daily)	Daily dose of Testogel 16.2 mg/g gel	No. pump actuations of Testogel 16.2 mg/g gel (once daily)
25 mg	Half of a sachet	20.25 mg	1 actuaction
50 mg (recommended starting dose)	1 sachet	40.5 mg (recommended starting dose)	2 actuactions
75 mg	1.5 sachet	60.75 mg	3 actuactions
100 mg	2 sachets	81 mg	4 actuactions

Simple and convenient once-daily application

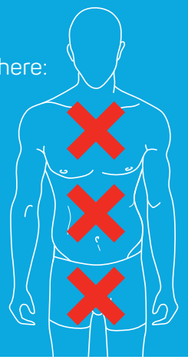
Application site for new Testogel 16.2 mg/g gel[2]

Simply apply a thin layer to the shoulders and upper arms once-a-day in the morning, leave to dry and then dress. No need to rub. Dries in 3 to 5 minutes

You should only apply Testogel 16.2 mg/g gel to these sites:



Not here:



Besins Healthcare has developed a patient support programme intended to:

www.testogelpump.co.uk/patient

> Aid understanding of testosterone deficiency

> Inform on how to use Testogel 16.2mg/g gel

> Support adherence to testosterone therapy

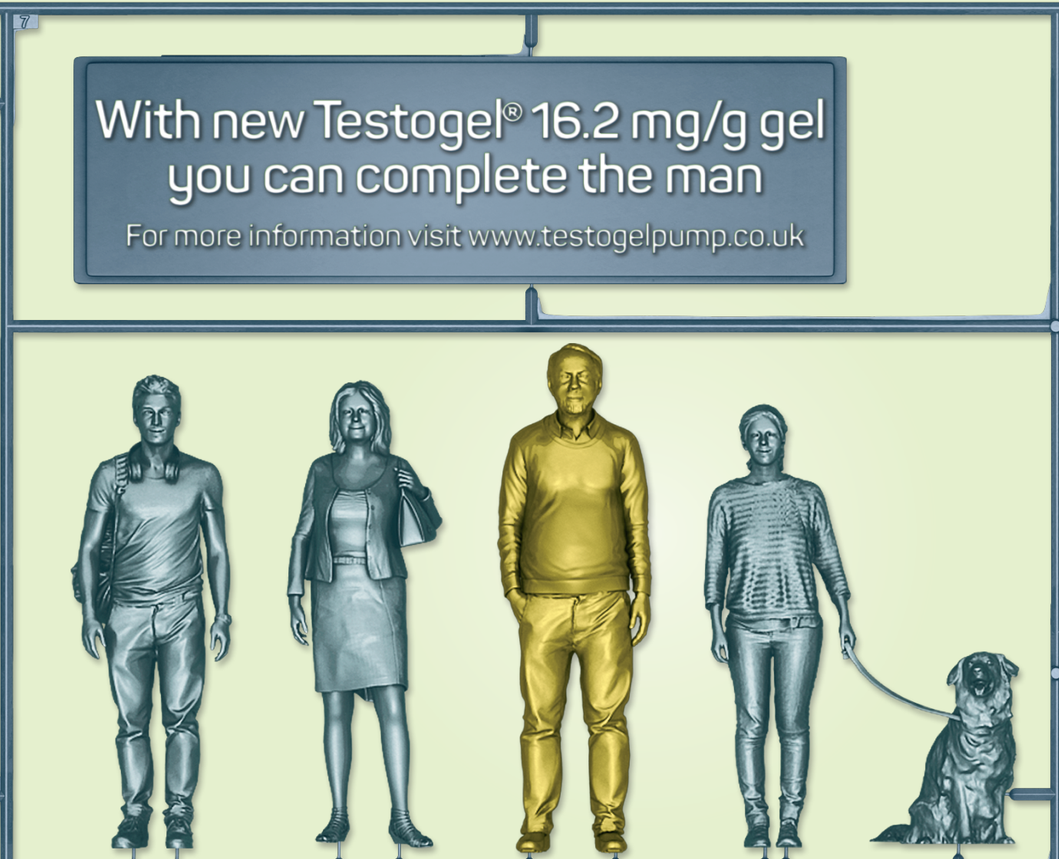
Patients can be informed about the website by using the Testogel 16.2 mg/g gel Patient information booklet.

While holding on to the reassurance of Testogel 50 mg gel...

> Testogel 50 mg gel is the number one selling testosterone replacement therapy worldwide[1]

With new Testogel® 16.2 mg/g gel you can complete the man

For more information visit www.testogelpump.co.uk



Move over to new Testogel 16.2 mg/g gel

Comes in an easy to use pump with additional benefits compared to Testogel 50 mg gel:

> Easier to titrate[2]

> Smaller volume of gel[3]

> Potential cost saving

> Informative patient support programme[6]

Give him back what matters with Testogel® 16.2 mg/g gel

Abbreviated Prescribing Information Testogel® 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. 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 may increase the risk of sleep apnoea in patients who are obese or at risk of 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, 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 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 **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:** November 2017 TES/2017/013

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 Besins Healthcare (UK) Ltd, 28 Poland Street, London, W1F 8QN. Tel: 0203 862 0920. Email: pharmacovigilance@besins-healthcare.com

References: 1. IMS Health. Internal calculations based on IMS Health, IMS MIDAS MAT Q3 2017 (LCD/MNF). 2. Testogel 16.2 mg/g Summary of Product Characteristics. 3. Kaufman JM et al. J Sex Med. 2012; 9(4): 1149–1161. 4. MIMS Testogel 16.2 mg/g 5. Testogel 1% Summary of Product Characteristics. Available at http://www.medicines.org.uk/emc/medicine/12391 6. http://testogelpump.co.uk/patient/
Date of Preparation: January 2018. TES/2018/002.

PIP Code 406-7922

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