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

David 57

Information for pharmacists about Testogel[®] 40.5 mg, transdermal gel in sachet replacing the Testogel[®] 50 mg 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

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 sachet.

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 |

This leaflet will provide you with key information to ensure you and your patients are ready for the new 40.5 mg formulation.



THE TESTOGEL® 40.5 MG SACHET AND TESTOGEL® 16.2 MG/G PUMP ARE INTERCHANGEABLE, GIVING PATIENTS THE FLEXIBILITY TO EASILY SWITCH BETWEEN THE PRODUCTS.^{1,4}

Dispensing Testogel® products

Prescriptions for testosterone therapy may be written either stipulating the Testogel® brand name or non-proprietary name. However, the difference in the product names should still make it simple to dispense the intended formulation for each Testogel® patient.

Please note that Testogel® 40.5 mg sachet and Testogel® 16.2 mg/g gel pump are interchangeable. Therefore, patients may be prescribed both products. If both products have been prescribed, please check with the patient that this was discussed with their doctor and that they are aware that the dosing differs between the pump and sachet.

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.^{1,4}

Example Testogel® prescriptions⁵

| | | |
|--|--|--|
|  |  |  |
| Branded prescription: Testogel® 50 mg transdermal gel in sachet ³ | Branded prescription: Testogel® 16.2 mg/g gel ⁴ | Branded prescription: Testogel® 40.5 mg transdermal gel in sachet ¹ |
| Non-proprietary prescription: Testosterone 50 mg in sachet | Non-proprietary prescription: Testosterone 16.2 mg/g | Non-proprietary prescription: Testosterone 40.5 mg in sachet |
| | | Available from 14th February 2022 |

BESINS HEALTHCARE PROVIDES A PATIENT SUPPORT PROGRAM FOR TESTOGEL® PATIENTS, TO HELP INSTIL CONFIDENT, REGULAR USE OF TREATMENT, SUPPORTING PATIENT COMPLIANCE AND BETTER CLINICAL OUTCOMES.

HELP YOUR PATIENTS STAY ON TRACK AND IN CONTROL OF THEIR TREATMENT WITH TESTOGEL.CO.UK AND THE T TRACK APP.

FAQs—what questions might my patients ask?

Will the lower dose of the new sachet still work as well?





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 therefore required to apply the recommended dose, making application more convenient for patients.

Testogel® 40.5 mg, 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.⁶

2017 BSSM Guidelines recommend a target therapeutic range of 15–30 nmol/L.⁷

How do I apply Testogel® 40.5 mg sachet?

| | |
|---|---|
|  | <p>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/per day, washing hands after application.</p> <p>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}</p> |
|  | <p>No application site rotation or dose applicator is required.</p> |
|  | <p>Allow the gel to dry for at least 3–5 minutes before dressing.</p> <p>Testogel® 40.5 mg, transdermal gel in sachet is flammable until dry.</p> |
|  | <p>Recommended period between application and showering/bathing is 1 hour.</p> <p>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.</p> |

Do I need to store this sachet in the fridge?

No. Testogel® 40.5 mg, transdermal gel in sachet has no special storage conditions and should be stored in a cupboard or drawer, out of reach of children.¹

Can I switch between my Testogel® pump and the 40.5 mg, transdermal gel in sachet?

Yes, if both formulations have been prescribed by your doctor, as the 40.5 mg sachet contains the same 16.2 mg/g gel found in the Testogel® pump.

Patients switching between the pump and sachet 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.^{1,8}

Previously, patients have been prescribed 2 x 50mg sachets per day equalling 100mg of testosterone. How will this change for the 40.5mg sachet?

Doctors may prescribe their patients up to 2 x 40.5mg sachets per day to be applied to the upper arms and shoulders, equalling 81mg which is the maximum daily dose for Testogel 40.5mg.

PLEASE NOTE: patients could apply Testogel 50 mg to their abdomen, which is not recommended for Testogel 40.5 mg

What are the most common side 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, 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

Four key things to take away

- The new Testogel® 40.5 mg sachet contains the same formulation as the 16.2 mg/g gel Testogel® pump
- Testogel® 40.5 mg is a more concentrated gel than Testogel® 50 mg. This means patients need less volume of gel to apply the recommended dose for the 40.5 mg making it more convenient to apply than the 50 mg.^{1,3}
- The 40.5 mg sachet and 16.2 mg/g gel in pump are interchangeable and patients should be made aware that the dosing differs^{1,4}
- Besins Healthcare provides a Patient Support Program for Testogel® patients, to help instil confident, regular use of treatment, supporting patient compliance and better clinical outcomes.

Please click [here](#) for prescribing information.

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.
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5. National Institute for Health and Care Excellence (NICE). Testosterone, Gel. Available at: <https://bnf.nice.org.uk/medicinal-forms/testosterone.html>. Accessed March 2022.
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8. 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.