# Testogel® 40.5mg Sachet: Off label FAQs

**The following are standard responses for use by Besins Healthcare (UK) Ltd medical personnel and medical information teams to respond to enquiries from Healthcare Professionals. They are not a substitute for the Summary of Product Characteristics which should be used as the primary reference for medical information enquiries.**

**The information contained within this document (either in full or in part) may be used to respond to individual enquiries from members of the health professions or other relevant decision makers, but only if they relate solely to the subject matter of the enquiry**

## Why do I have to change my patients' medication? Can I keep my female patients on their existing medication?

Like all companies, Besins Healthcare (UK) Ltd regularly review our portfolio. As a result of a portfolio management exercise, we have decided to harmonise our product range. This has enabled our products to be interchangeable and offer greater flexibility for prescribers and patients. Besins Healthcare (UK) Ltd are phasing out the Testogel® 50 mg sachet and therefore it will no longer be available for prescribing.

## Is the new Testogel® 40.5mg sachet gel the same as the Testogel® 50mg sachet gel?

No. The gel in the new Testogel® 40.5mg sachet contains a higher concentration of the active ingredient, testosterone, as well as increased concentrations of other components of the gel which increase the viscosity and in-vitro permeability of the gel. This means that patients will be able to apply less gel as compared to the existing formulation.[1,2,3]

Please note that studies to evaluate the efficacy and safety of the gel contained in the Testogel® 40.5mg sachet were conducted in male patients. There is no clinical data on females treated with this product.

## Will my female patients feel any different on a 5mg dose of the new medication?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

Despite the gel in the new Testogel® 40.5mg sachet being more concentrated and more viscous compared to the gel in the existing Testogel® 50mg sachet, it is still possible for patients to administer a 5mg daily dose of testosterone so if the equivalent dose is administered, it is not expected that patients will feel a difference in the effects of the product. [1]

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The gel in the new Testogel® 40.5mg sachet will however feel different when applying compared to the existing Testogel® 50mg sachet. There will be less gel to apply but it will feel thicker or more viscous.[1]

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## How do the components of the new gel compare to the existing formulation? Will the new gel feel the same when my female patients apply it?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

The testosterone gel contained in the 40.5mg sachet was developed to improve the viscosity and to reduce the volume of application in order to create a more patient-friendly gel. The gel was developed by optimising the levels of existing components in the Testogel® 50mg sachet.[1] Different formulas were tested during development to find the best combination.[4]

The new Testogel® 40.5mg sachet contains higher concentrations of testosterone as well as other components which together increase both viscosity and in-vitro skin permeability.[1,2]

The gel in the new Testogel® 40.5mg sachet will therefore feel different compared to the existing Testogel® 50mg sachet. There will be less gel to apply but it will feel thicker or more viscous.[1]

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## Are there additional side effects that I need to inform my female patients about?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

The side effects of Testogel® 40.5 mg are very similar to Testogel® 50 mg.[5,6,7] 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. However, it needs to be stressed that these side effects were reported based on the licensed use of the product. Please refer to the full summary of product characteristics for a full list of side effects. [5,6,7]

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## How do I inform my female patients how they can apply a 5mg daily dose of testosterone using the new sachet?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

The Testogel® 40.5mg sachet contains a more concentrated gel with increased viscosity compared to the current Testogel® 50mg sachet.[1,3] This means that patients will need less gel in order to apply a 5mg daily dose of testosterone. See below for further detail.

The following calculations are based on the density of gel in both preparations being approximately 0.88g/mL.[8]

| **Testogel® 50mg Sachet** | **Strength = 10mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 5 | 0.5 | 0.57 |

| **Testogel® 40.5mg Sachet** | **Strength = 16.2mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 5 | 0.31 | 0.35 |

Please note that studies to evaluate the efficacy and safety of the gel contained in the Testogel® 40.5mg sachet were conducted in male patients. There is no clinical data on females treated with this product.

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## Will there be a difference in the length of time the new sachets will last if I advise my female patients to apply a 5mg dose each day?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

At a daily 5mg dose of testosterone (0.5g/0.57mL of gel), the current Testogel® 50mg sachet should last approximately 10 days. At a daily 5mg dose of testosterone (0.31g/0.35mL of gel), the new Testogel® 40.5mg sachet should last approximately 8 days.[5,6,7]

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## What are the differences in testosterone concentration between the existing Testogel® 50mg sachet and the new Testogel® 40.5mg sachet?

The Testogel® 50mg sachet contains a 1% testosterone gel. This can also be depicted as 10mg/g. Simply put, there is 10mg of testosterone in each gram of gel. Each sachet of Testogel® 50mg is 5g in weight. Therefore, if there is 10mg of testosterone in each gram of gel that means that each sachet contains (10mg x 5) 50mg of testosterone.[6,7]

The new Testogel® 40.5mg sachet contains a 1.62% or 16.2mg/g gel. Again, for simplicity, this means that there is 16.2mg of testosterone in each gram of gel. However, each sachet of Testogel® 40.5mg is only 2.5g in weight. Therefore, if there is 16.2mg of testosterone in each gram of gel that means that each sachet contains (16.2mg x 2.5) 40.5mg of testosterone. [5]

## Can my female patients apply the gel to the same application site that they currently do?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

The licensed application sites for the 2 products does differ. Testogel® 40.5 mg should be applied to the shoulders and upper arms only. The existing Testogel® 50mg can be applied to the shoulders, upper arms AND the abdomen. The key difference is therefore that the Testogel® 40.5mg cannot be applied to the abdomen.[5,6,7]

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## Will my female patients need to change the amount/volume of gel they apply each day to administer a 5mg dose of testosterone if I change their medication to the new Testogel® 40.5mg sachet?

Testogel® 40.5 mg is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. This medicine is intended for use by men only. This medicine is not indicated in pregnant women, due to potential virilising effects of the foetus.

Pregnant women must avoid any contact with this medicine's application sites. In the event of contact, wash with soap and water as soon as possible. This medicine is not indicated in women who are breast-feeding. Spermatogenesis may be reversibly suppressed with this medicine.

Due to the increased concentration of testosterone contained in the new Testogel® 40.5mg sachet, patients do not require the same volume of gel in order to apply a 5mg daily dose.[1,5] It is important that patients reduce the volume of gel applied as shown below. If patients continue to use the same volume of the new Testogel® 40.5mg sachet as they do currently with the existing Testogel® 50mg sachet patients will administer a higher dose of testosterone.[5,6,7,8]

The following calculations are based on the density of gel in both preparations being approximately 0.88g/mL.[8]

| **Testogel® 50mg Sachet** | **Strength = 10mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 5 | 0.5 | 0.57 |

| **Testogel® 40.5mg Sachet** | **Strength = 16.2mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 5 | 0.31 | 0.35 |

For illustrative purposes, if the same volume of gel from both sachets were to be applied by a patient, the daily dose would increase from 5mg to 8.1mg of testosterone.[5,6,7,8] See below.

| **Testogel® 50mg Sachet** | **Strength = 10mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 5 | 0.5 | 0.57 |

| **Testogel® 40.5mg Sachet** | **Strength = 16.2mg/g** |
|---|---|

| Testosterone (mg) | Grams of Gel (g) | Volume of Gel (mL) |
|---|---|---|
| 8.1 | 0.5 | 0.57 |

Besins cannot recommend the use of this product in any manner that is inconsistent with the SmPC.

## References


1. Data on file – BHUK/2022/038
2. Data on file – BHUK/2022/037
3. Kaufman J et al. Efficacy & Safety Study of 1.62% (16.2mg/g) Testosterone Gel for the Treatment of Hypogonadal Men. Journal of Sexual Medicine 2011; 8: 2079-2089
4. Data on file – BHUK/2022/039
5. Testogel 40.5mg sachet – Summary of Product Characteristics (SmPC) Accessed January 2022
6. Testogel 50mg Sachet – Summary of Product Characteristics (SmPC) Date of Revision 12th February 2021. Accessed Jan 2022

7. Testogel 50mg Sachet – Summary of Product Characteristics (SmPC) ROI Date of Revision 13th October 2020. Accessed Jan 2022
8. Data on file – BHUK/2022/036