

Testogel® 16.2 mg/g gel (testosterone)

Frequently Asked Questions

For internal use only

The following are standard responses for use by Besins Healthcare (UK & Ireland) personnel to respond to enquiries from Healthcare Professionals. They are not a substitute for the Summary of Product Characteristics¹ and Patient Information Leaflet² which should be used as the primary reference for medical information enquiries.

Why is this formulation of Testogel 16.2 mg/g referred to in mg/g instead of %?

According to the Quality Review of Documents (QRD)³ recommendations on the expression of strength in the name of centrally authorised human medicinal products published in 2009 by the European Medicines Agency (EMA), semi solid preparations in gel form should be expressed under the format 'x mg/g'.

How is Testogel 16.2 mg/g supplied?

Testogel 16.2 mg/g is supplied in a metered dose pump bottle which contains 60 usable pump presses, or a month's supply at the recommended dose of 2 pump presses once daily (20.25 mg of testosterone per pump press which equates to 1.25 grams of gel).

What does 16.2 mg/g relate to in the product name?

This simply means the quantity of testosterone (mg) that is delivered for every gram (g) of gel. For example - The recommended starting dose is 2 actuations which delivers 40.5mg of testosterone in 2.5g gel (16.2mg x 2.5g = 40.5mg)

¹ Testogel 16.2 mg/g gel SPC : <http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1496989585647.pdf>

² Testogel 16.2 mg/g gel PIL : <http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1496989585812.pdf>

³ QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500056428.pdf

Does it mean that Testogel 16.2 mg/g is a more concentrated/stronger preparation than Testogel 1 %?

The 16.2mg/g is a more concentrated gel as compared to the 1% (10mg/g). This means that patients can apply less gel to achieve comparable results. Be careful however when discussing strength as opposed to concentration. The 16.2mg/g delivers 40.5mg of testosterone vs 50mg of testosterone in a single 1% sachet as per recommended starting dose. Therefore, the patient is receiving 40.5mg vs 50mg so it is not a stronger preparation, just more concentrated.

What is the recommended daily dose of Testogel 16.2 mg/g ¹?

The recommended dose is two pump actuations of gel (i.e. 40.5 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 four pump actuations or 81 mg testosterone per day. The adjustment of posology should be achieved by increments of one pump actuation of gel.

The dose should be titrated based on the pre-dose morning testosterone blood levels. Steady state blood testosterone levels are reached usually by the second day of treatment with TESTOGEL 16.2 mg/g. In order to evaluate the need to adjust the testosterone dosage, blood testosterone levels should be measured in the morning before application of the product, after the steady state is reached. Testosterone blood levels should be assessed periodically. The dose may be reduced if the testosterone blood levels are raised above the desired level. If the levels are low, the dosage may be increased stepwise, to a maximum daily administration of 81 mg of testosterone (four actuations of gel) per day.

Is Testogel 16.2mg/g gel comparable to Testogel 50mg gel?

Yes

Even though there are no direct head-to-head studies, pharmacokinetic data suggests that comparable C_{avg} testosterone levels are achieved over 24 hours from 2 actuations of the 16.2mg/g pump (40.5mg) as compared to Testogel 50mg sachet:

- 5g of a 50mg sachet – At Day 180, T levels were 19.2nmol/L (*Swerdloff et al 2000*)⁴
- 2.5g of 16.2mg/g (40.5mg) – At Day 182, T levels were 17.1nmol/L (*Kaufman 2011*)⁵

Both of these achieved T levels are within the target therapeutic range of 15-30nmol/L which is the recommended level from the 2017 BSSM androgen guidelines⁶.

The safety & efficacy profile of the new 16.2mg/g gel appears to be comparable to 1% testosterone gels used in hypogonadal man.⁵

⁴ S. Swerdloff et al., Long-Term Pharmacokinetics of Transdermal Testosterone Gel in Hypogonadal Men, The Journal of Clinical Endocrinology & Metabolism, 2000.

⁵ Kaufman et al., Efficacy and Safety Study of 1.62% Testosterone Gel for the Treatment of Hypogonadal Men, The Journal of Clinical Endocrinology & Metabolism, 2011

⁶ Hackett et al., British Society for Sexual Medicine Guidelines on Adult Testosterone Deficiency, With Statements for UK Practice, The Journal of Sexual Medicine, 2017

What is the equivalent cost between Testogel 50mg gel and Testogel 16.2 mg/g based on the pivotal studies? ^(4,5)

**** Based on price parity i.e. £31.11 for both Testogel sachet & pump**

Dose	Swerdloff, R et al 2000 - (Day 91-180) [n=143] [^]			Dose	Kaufman, J et al 2011 - (Day 42-182) [n=234] ^{^^}		
	Testogel 50 mg sachet	No. of Sachets	Cost/30 Days		Testogel 16.2mg/g gel	Actuations	Cost/30 Days
				20.25mg	7%	1	£15.56
				40.5mg	26%	2	£31.11
50mg	36%	1	£31.11				
				60.75mg	28%	3	£46.67
75mg	28%	1.5	£62.22*				
				81mg	39%	4	£62.22
100mg	36%	2	£62.22				
Cost/100 patients = £5102.04 [(36 x £31.11) + (28 x £62.22) + (36 x £62.22)]				Cost/100 patients = £4651.12 [(7 x £15.56) + (26 x £31.11) + (28 x £46.67) + (39 x £62.22)]			
<p>*As per the SPC for the Testogel 50 mg sachets "After opening the sachets, the total contents must be extracted from the sachets and immediately applied to the skin" therefore partially used sachets cannot be suitably stored</p>							
<p>[^]The number of subjects enrolled in days 91–180 of the study consisted of 51 continuing 50 mg/day T gel, 40 receiving 75 mg/day T gel and 52 receiving 100 mg/day T gel</p>							
<p>^{^^}Subjects were maintained at their respective day 42 dose until day 182</p>							

Will Testogel 50 mg still be available?

Yes, Testogel 50mg sachets will still be available however we recommend the use of Testogel 16.2mg/g for a number of reasons:

- Returns testosterone level within the normal range with a smaller, more concentrated volume of gel
- Simple to initiate
- Well tolerated
- NHS Price of £31.11, equivalent to Testogel 50mg gel

How do I transfer a patient from Testogel 50mg gel to the Testogel 16.2 mg/g? ^(5,9)

If a patient is on the sachet they can be transferred the following day to the pump formulation.

Testogel 50g x 1 sachet - 2.5g of Testogel 16.2 mg/g ie 2 pump actuations.

Testogel 50mg x 2 sachets - 5g of Testogel 16.2 mg/g ie 4 pump actuations

As with all testosterone replacement treatments, patients should be monitored regularly to ensure they are on the correct dosage.

Are the ingredients in Testogel 16.2 mg/g and Testogel 50mg the same?

Testogel 16.2mg/g contains the same ingredients as Testogel 50mg. However, the testosterone is more concentrated, and the proportion of the other ingredients is slightly different.⁷

⁷ Besins manufacturing Belgium : module 3.2.P.1 – Description & Composition

What are the application sites for Testogel 16.2 mg/g and why is the abdomen not an application site for Testogel 16.2 mg/g?

Testogel 16.2 mg/g should be applied to clean, dry, intact skin of the upper arms and shoulders. Do not apply Testogel 16.2 mg/g to any other parts of the body, including the abdomen or genitals.

Less Testogel is absorbed when applied abdominally, therefore Testogel 16.2mg/g should be applied to the upper arms and shoulders ¹

Can I swim or shower after using Testogel 16.2mg/g?

Patients should wait at least 2 hours after applying Testogel 16.2 mg/g before showering or swimming. Ideally leave at least 6 hours between gel application and bathing or showering. Occasional baths or showers taken between 1 and 6 hours after application of the gel should not significantly influence the treatment outcome. ¹

What precautions do I need to take in relation to possible transfer of Testogel 16.2 mg/g to a partner or children? ¹

The physician should inform the patient carefully about the risk of testosterone transfer and about safety instructions. TESTOGEL 16.2 mg/g should not be prescribed in patients with a major risk of non-compliance with safety instructions (e.g. severe alcoholism, drug abuse, severe psychiatric disorders).

The potential risk of transfer is substantially reduced (but not eliminated) by wearing clothes (such as a sleeved shirt) covering the application area. The majority of residual testosterone is removed from the skin surface by washing with soap and water prior to contact.

The following precautions are recommended:

For the patient:

- wash hands with soap and water after applying the gel
- cover the application area with clothing (such as a sleeved shirt) once the gel has dried
- shower and wash the application site(s) thoroughly with soap and water to remove any testosterone residue before any situation in which close contact is foreseen

For people not being treated with TESTOGEL 16.2 mg/g:

- in the event of contact with an application area that has not been washed or is not covered with clothing, wash the area of skin onto which testosterone may have been transferred as soon as possible using soap and water

To improve partner safety, the patient should be advised, for example, to wash the area with soap for instance during a shower before sexual intercourse or, if not possible, wear clothing such as a shirt or a T-shirt covering the application site during the contact period.

Furthermore, it is recommended to wear clothing covering the application site (such as a sleeved shirt) during contact periods with children, in order to avoid the risk of contamination of children's skin.

Pregnant women must avoid any contact with TESTOGEL 16.2 mg/g application sites. In case of pregnancy of a partner, the patient must pay extra attention to the precautions for use described above

Can I take Testogel 16.2 mg/g when travelling in my carry-on luggage?

You're allowed to carry essential medicines of more than 100ml in your hand luggage, but you need supporting documentation from a relevant medical professional (eg a letter from your doctor or a copy of your prescription). The same applies for gel packs. Airport staff might need to open the containers to screen the liquids at the security point.⁸

The volume of gel in the pump is approximately 100ml, however the label only indicates 88g so we would recommend either putting the medicine in the hold luggage or carrying it separately from other liquids with a letter from your doctor or a copy of your prescription. At security, you must present all liquid, aerosol and gel medication for inspection. Following x-ray screening, security officers may also need to carry out additional checks on these items. As with taking any medicine abroad, we would also recommend you check the requirements of the country you are visiting

What is the source of testosterone in Testogel 16.2 mg/g?

The testosterone in Testogel is derived from the yam plant. The extract goes through enzymatic reactions to produce androstenedione, from which testosterone is obtained.

What is the shelf-life of Testogel 16.2 mg/g?

3 years¹

How do I prescribe Testogel 16.2 mg/g?

On prescribing systems, the name of the product will appear as brand and as a generic. They will be shown as follows⁹:

- Brand description: Testogel 16.2mg/g gel (testosterone)
- Generic description: Testosterone 16.2mg/g gel

Comparable dosing of Testogel 16.2 mg/g gel and Testogel 50 mg gel is as follows^(1, 10)

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

⁸ <https://www.gov.uk/hand-luggage-restrictions/essential-medicines-and-medical-equipment>

⁹ <http://dmd.medicines.org.uk/DesktopDefault.aspx?AMP=35020311000001107&toc=nofloat>

¹⁰ Testogel 50 mg gel SPC : <http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1512713089677.pdf>