

FREQUENTLY ASKED QUESTIONS ON HYPOGONADISM AND TESTOGEL (TESTOSTERONE) 16.2 MG/G GEL

GENERAL QUESTIONS

What is hypogonadism?

Male hypogonadism (also known as testosterone deficiency) is defined as a clinical and biochemical syndrome associated with advancing age and comorbidities. It is characterised by a deficiency in serum androgen levels and relevant signs and symptoms, including low mood, fatigue, reduced muscle mass and decreased libido.¹

Testosterone has many effects on the body, including primary sexual development and regulation of secondary male characteristics. It's important for a man's physical and emotional well-being, including maintaining muscle and bone mass, the production of sperm and libido – amongst other things.¹

At what level of testosterone, in patients with testosterone deficiency, should I consider treating with testosterone replacement therapy?

Regarding the thresholds for treatment intervention in symptomatic men, the British Society for Sexual Medicine and International Society for Sexual Medicine guidelines recommend the following:¹

- A testosterone level lower than 8 nmol/L or free-testosterone level lower than 0.180 nmol/L based on 2 separate levels (taken from 8 to 11 AM) usually requires testosterone therapy.
- A testosterone level higher than 12 nmol/L or free testosterone level higher than 0.225 nmol/L does not usually require testosterone therapy.
- Testosterone level from 8 to 12 nmol/L might require a trial of testosterone therapy for a minimum of 6 months based on symptoms.

PRESCRIBING TESTOGEL 16.2 MG/G GEL

What is Testogel 16.2mg/g gel?

Testogel 16.2 mg/g gel is a prescription only medicine that contains testosterone. Testogel 16.2 mg/g gel is indicated in adults as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. Testogel 16.2 mg/g gel is not indicated for use in women.²

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

This simply means the quantity of testosterone (mg) that is delivered for every gram (g) of gel.

Why is this formulation of Testogel 16.2 mg/g gel 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'.

On prescribing systems, the name of the product may appear as brand and as a generic. They may be shown as follows ⁴

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

| | Daily dose of testosterone | No. actuations of Testogel 16.2 mg/g gel once daily |
|-------------------|----------------------------|---|
| Lowest daily dose | 20.25 mg | 1 actuation |
| Recommended dose | 40.5 mg | 2 actuations |
| Maximum dose | 81 mg | 4 actuations |

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

The recommended dose is two pump actuations of gel (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.²

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 gel. 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.²

How is Testogel 16.2 mg/g gel supplied?

Testogel 16.2 mg/g gel is supplied in a multi-dose container with metering pump that contains 88 g of gel and delivers a minimum of 60 doses. At the recommended dose of 2 pump actuations (40.5 mg of testosterone), the pump container should supply 1 month of treatment. Each actuation delivers 20.25 mg of testosterone in 1.25 g of gel.

Are Testogel 16.2 mg/g gel and Testogel 50 mg, gel in sachet interchangeable?

No. Dosing and application sites for Testogel 16.2 mg/g gel differ from Testogel 50 mg and therefore the products are not interchangeable.^{2,5}

How do I transition from Testogel 50 mg to Testogel 16.2 mg/g pump?

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.

Enquirers should be advised that they should refer to the individual products' summary of product characteristics for guidance related to starting/recommended dose and titration of the particular Testogel formulation (section 4.2).

Is Testogel 16.2 mg/g a more concentrated or a 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. 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.

Who should not use Testogel 16.2 mg/g gel? ²

Testogel 16.2 mg/g is contraindicated:

- in case of known or suspected prostate cancer or breast carcinoma
- in case of known hypersensitivity to testosterone or to any of the excipients listed in section 6.1 of the SPC

The safety and efficacy of Testogel 16.2 mg/g in males under 18 years have not been established. Testogel 16.2 mg/g gel is not indicated for use in women and must not be used in women who are or may become pregnant or are breastfeeding.

Testogel 16.2 mg/g gel may harm the unborn or breastfeeding baby. Women who are pregnant or may become pregnant should avoid contact with the area of skin where Testogel 16.2 mg/g gel has been applied.

What assessment should be carried out before initiating Testogel 16.2 mg/g gel and monitoring requirement after treatment?

Testosterone deficiency should be diagnosed on the basis of:^{1,2}

- Signs and symptoms
- Two fasting Total Serum Testosterone tests on separate occasions carried out between 7-11am

Prior to testosterone initiation, all patients must undergo a PSA test and a digital rectal examination to exclude a risk of pre-existing prostate cancer.²

Patients on testosterone should be monitored by:

- PSA test at 3-6 months after starting treatment and then annually.
- Haematocrit, haemoglobin, testosterone, liver function and lipids should be monitored periodically.

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

3 years.²

Can patients take Testogel 16.2 mg/g with them when travelling with only carry-on luggage?

People are allowed to carry essential medicines of more than 100ml in hand luggage, but they need supporting documentation from a relevant medical professional (e.g. a letter from a doctor or a copy of a prescription). The same applies for gel pumps. Airport staff might need to open the containers to screen the liquids at the security point.⁶ The volume of gel in the pump is approximately 100ml, however the label only indicates 88g so it is recommended to either put the medicine in the hold luggage or carrying it separately from other liquids with a letter from a doctor or a copy of a prescription. At security, all liquid, aerosol and gel medication should be presented 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 recommend you check the requirements of the country you are visiting.

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

APPLICATION OF TESTOGEL 16.2 MG/G GEL

What are the application sites for Testogel 16.2 mg/g gel?

Testogel 16.2 mg/g gel should be applied to clean, dry, intact skin of the upper arms and shoulders. Do not apply Testogel 16.2 mg/g gel to any other parts of the body, including the genitals as the high alcohol content may cause local irritation.²

What precautions need to be taken to prevent possible transfer of Testogel 16.2 mg/g gel?

You should inform the patient carefully about the risk of testosterone transfer to a partner or children and about safety instructions. Testogel 16.2 mg/g gel 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 gel:

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, to avoid the risk of contamination of children's skin.

Pregnant women must avoid any contact with Testogel 16.2 mg/g gel application sites. In case of pregnancy of a partner, the patient must pay extra attention to the precautions for use described above.²

References

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