

**Bedfordshire, Luton and Milton Keynes Area Prescribing Committee  
(BLMK APC)**

# **Testosterone Gel for low sexual desire in post-menopausal women – Fact Sheet**

**Version 1.3, January 2023**

Version Control	
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Checked by	Taiya Large, BLMK ICB
Review	Nov 2024

Change control

Update:	Date:
Testogel strength and dosing advice updated following discontinuation of 50mg/5g strength (replaced with 40.5mg in 2.5mL over 8 days)	22.4.22
Removal of testing requirements FAI and SHBG	8.11.22
Addition of safety alert	30.1.23

# Testosterone Gel for low sexual desire in post-menopausal women – Fact sheet

## Background

The Bedfordshire, Luton and Milton Keynes (BLMK) Formulary Subgroup to the Area Prescribing Committee (APC) agreed the following recommendations in September 2021 (These recommendations have been ratified by the APC):

- The committee agreed that Testosterone gel (Testogel®/Tostran®) for treating the symptom of low sexual desire in post-menopausal women is added to both Joint Formularies in accordance with the recommendations included in NICE Guideline 23 i.e. if HRT alone is not effective.
- GPs may continue therapy after initiation and stabilisation by a clinician with expertise in the treatment of the menopause (Defined as a Consultant Endocrinologist/Gynaecologist or a Primary Care Clinician who has relevant experience and is clinically competent to prescribe).
- Notes to be added to each formulary to clarify the meaning of 'specialist' (see above).
- Fact sheet to be developed to assist GPs in taking over prescribing, including guidance regarding blood monitoring requirements and patient counselling.
- No prescribing until fact sheet developed and agreed.

## Formulary status:

- Bedfordshire and Luton – Amber
- Milton Keynes - Amber 3

Further information relating to the use of testosterone gel for treating symptoms of low sexual desire in post-menopausal women can be accessed from the British Menopause Society (BMS) Tool kit. [Click here](#) to access it.

[Click here](#) for a patient information leaflet produced by the British Menopause Society

<b>Medicine (Generic and Brand name)</b>	Testosterone gel (Testogel® or Tostran®)
<b>Strength and formulation</b>	Testogel® 40.5mg/2.5g transdermal gel in sachets Tostran® 2% Gel in a canister containing 60g
<b>Intended indication</b>	<p>Low sexual desire in postmenopausal women (administered on expert advice) - NB this is an 'off label' use of testosterone gel.</p> <p>For use as outlined in <a href="#">NICE Guideline 23 – Menopause: diagnosis and management:-</a></p> <div style="border: 1px solid black; padding: 5px;"> <p><b>Altered sexual function</b> 1.4.8 Consider testosterone supplementation for menopausal women with low sexual desire if HRT alone is not effective.</p> </div> <p>The NICE Guidance also states:</p> <p><b>If a woman has menopausal symptoms, consider arranging referral to a healthcare professional with expertise in menopause if:</b></p> <p>The women has persistent altered sexual function and hormonal and/or non-hormonal, or non-drug treatments are ineffective:</p> <ul style="list-style-type: none"> <li>• Seek specialist advice regarding the use of testosterone supplementation (off-label use)</li> </ul>

	<ul style="list-style-type: none"> <li>• Consider referral for psychosexual counselling, depending on the woman's wishes.</li> </ul>
<b>Safety and side effects</b>	<ul style="list-style-type: none"> <li>• Testosterone is well tolerated in the short term - symptoms of androgen excess, such as hirsutism and acne, are common with testosterone therapy, although these effects are often mild.</li> <li>• If adverse effects are thought to be linked to testosterone gel usage, the dosage used should be reduced or treatment stopped. Where increased body hair occurs at the site of application – spread more thinly, vary the site of application, reduce dosage.</li> <li>• The safety of long-term testosterone therapy has not been established, particularly with regard to lipids, cardiovascular disease and breast cancer. It should be noted that many of the clinical trials excluded women with cardiometabolic risk.</li> <li>• MHRA DSU Jan 2023: <a href="#">Topical testosterone (Testogel): risk of harm to children following accidental exposure</a></li> </ul> <p>Premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine. To reduce these risks, advise patients to wash their hands after application of topical testosterone, cover the application site with clothing once the product has dried, and wash the application site before physical contact with another adult or child.</p>
<b>When should testosterone be avoided or used with caution?</b>	<ul style="list-style-type: none"> <li>• During pregnancy or breastfeeding</li> <li>• Active liver disease</li> <li>• History of hormone sensitive breast cancer – off label exceptions to this may be agreed in fully informed women with intractable symptoms not responding to alternatives</li> <li>• Competitive athletes – care must be taken to maintain levels well within the female physiological range</li> <li>• Women with upper normal or high baseline testosterone levels.</li> </ul>
<b>Dose and administration</b>	<p><b>For Adults</b></p> <p><b>Testogel®:</b> Apply 40.5 mg over an 8 day period, the contents of a 2.5g sachet to be divided for daily dosing and applied to non-hairy areas, such as the abdomen or upper thighs.</p> <p><b>Tostran®:</b> Starting dose 1 metered pump or 0.5g =10mg on alternate days. Each canister should last 240 days</p> <p>The testosterone gel should be to applied to clean dry skin (lower abdomen/upper thighs) and allowed to dry before dressing. Skin contact with partners or children should be avoided until dry and hands should be washed immediately after application. The area of application should not be washed for 2-3 hours after application.</p> <p>When treating low sexual desire /arousal it is also important that urogenital tissues are adequately oestrogenised in women with vulvovaginal atrophy / genitourinary syndrome of the menopause e.g. through use of vaginal oestrogen, to avoid dyspareunia.</p> <p><i>Ref: British Menopause Society update on HRT supply Last updated: 12 April 2022 <a href="#">British Menopause Society update on HRT supply - British Menopause Society (thebms.org.uk)</a></i></p> <p><i>Ref - Testosterone replacement in menopause, tools for clinicians, British Menopause Society Published February 2019 <a href="https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause/">https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause/</a></i></p>

	<p>Ref – <i>Electronic BNF</i> – accessed 16/08/21 (and checked 11/10/21)  <a href="https://bnf.nice.org.uk/drug/testosterone.html#indicationsAndDoses">https://bnf.nice.org.uk/drug/testosterone.html#indicationsAndDoses</a></p>									
<b>Patient monitoring</b>	<p>NICE Guideline 23 recommends that each treatment for short-term menopausal symptoms should be reviewed:</p> <ul style="list-style-type: none"> <li>• At 3 months to assess efficacy and tolerability.</li> <li>• Annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side-effects or adverse events).</li> </ul> <p>The BMS recommends a 3-6 month trial of therapy. Duration of use should be individualised and evaluated at least on an annual basis, weighing up pros and cons according to benefits and risks, as per HRT advice from all menopause societies.</p>									
<b>Blood Test Monitoring</b>	<table border="1"> <thead> <tr> <th>Recommended Monitoring</th> <th>Total Testosterone</th> </tr> </thead> <tbody> <tr> <td>Baseline (before initiation of therapy)</td> <td>Yes</td> </tr> <tr> <td>After initiation or increase in dosage</td> <td>At 6 weeks, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)</td> </tr> <tr> <td>After downward dose titration (if total testosterone high, even if no androgenic side-effects)</td> <td>At 2-3 weeks, then at 3 months, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)</td> </tr> </tbody> </table> <p>It is recommended that <b>total testosterone levels</b> are checked before treatment to establish a baseline for future monitoring and to ensure that levels are not in the upper range before treatment is commenced.</p> <p>It is also recommended by some guidelines that testosterone levels are reassessed at 3-6 weeks after treatment is commenced, but given that most national health service clinics review their patients after 2-3 months it is recognised that this is an aspirational goal and that testing should be performed as close to this timeline as possible.</p> <p>It is important that monitoring continues every 6-12 months to ensure that levels remain within the female physiological range in order to minimise adverse effects.</p> <p><i>References: The above information is based on The BMS Tools for clinicians Testosterone replacement in menopause <a href="https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause/">https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause/</a> May 2022</i></p>		Recommended Monitoring	Total Testosterone	Baseline (before initiation of therapy)	Yes	After initiation or increase in dosage	At 6 weeks, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)	After downward dose titration (if total testosterone high, even if no androgenic side-effects)	At 2-3 weeks, then at 3 months, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)
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<b>Prescribing and monitoring Responsibilities</b>	<p>As patient assessment and selection is key, treatment should be initiated and stabilised by an expert (Defined as a Consultant Endocrinologist/Gynaecologist or a primary care clinician who has relevant experience and is clinically competent to prescribe) in treatment of the menopause. GP to continue therapy after the patient is stabilised on therapy, typically after a 6 month trial and conduct the patient annual review (unless there are clinical indications for an earlier review). All blood test monitoring (see above) will be undertaken by the clinician who is prescribing for the patient.</p>									

<p><b>Criteria for seeking further advice/referral back to expert in the treatment of the menopause</b></p>	<p>The following are examples:</p> <ul style="list-style-type: none"> <li>• Adverse Drug Reaction</li> <li>• Advice on Blood test monitoring</li> <li>• Diagnosis of new complex medical conditions</li> </ul>
<p><b>Private to NHS Care</b></p>	<p>As per the BLMK policy on Defining the Boundaries between NHS and Private Healthcare, after recommendations from a private consultant/specialist, GPs should only take on prescribing of testosterone Gel for low sexual desire in post-menopausal women if the patient's clinical circumstances meet the initiation criteria set out in NICE CG 23 and this bulletin. GPs should also be sure that the private consultant/specialist has expertise in managing the menopause and is following the prescribing and monitoring responsibilities set out in this bulletin.</p> <p>As with all recommendations to prescribe from a private consultant/specialist, GPs do also not have to take on prescribing if in the exercise of their clinical discretion they do not think it is medically appropriate for the patient, the testosterone preparation is not listed on the BLMK formulary or they are unwilling to accept clinical responsibility for prescribing the medication.</p> <p>We are aware of requests made by private consultants/specialist and patients following a private consultation for GPs to prescribe <i>AndroFeme [Lawley Pharma] (1% testosterone cream)</i>. AndroFeme is not currently available on the NHS and is being imported from Western Australia by special license from the MHRA. Therefore, patients will have to continue to fund this privately or the private consultant/specialist will need to recommend an alternative.</p>