PRESCRIBING TESTOSTERONE FOR POSTMENOPAUSAL WOMEN

Information for Primary Care Providers

While Testosterone is most likely to be of benefit to younger women who have had their ovaries removed, increasing numbers of women who have had a natural menopause are requesting it in the hope that it may improve their energy and libido. Although this demand is largely media driven, testosterone replacement is endorsed by the **British Menopause Society** as a hormonal treatment for hypoactive sexual desire disorder (HSDD) in postmenopausal women, when other causes have been excluded/treated www.thebms.org.uk– see tools for clinicians, testosterone replacement.

Unfortunately, at present in the UK there is no licensed preparation for testosterone replacement in women. In the past, testosterone patches were licensed for use in women with HSDD following surgical menopause who were on concomitant oestrogen; although similar efficacy and safety data also exist for natural menopause, and for women not using concomitant HRT. The licenses for patches and testosterone implants were both withdrawn for commercial reasons only, with the safety and efficacy data for these products remaining valid. By extrapolation of this data, it is deemed acceptable for products licensed for men (mainly gels) to be prescribed off label at doses appropriate for women. It is not uncommon in clinical practice to use medicines out with their product licence, as long as this meets the criteria proposed by the GMC and MHRA on prescribing an unlicensed medicine or using a medicine off-label. Criteria which should be met for 'off label' prescribing include: no suitably licensed products available / sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy / a clear record of reasons for prescribing an unlicensed medicine should be made / patients, or those authorising treatment on their behalf, should be given sufficient information about the proposed treatment.

What is the most suitable form of Testosterone?

Tostran 2% testosterone gel [Kyowa Kirin Ltd] (in a canister containing 60g)
is the preparation most suitable for prescribing in primary care, due to ease and accuracy of dosing.
Dose: 1 metered pump of 0.5g which contains 10mg testosterone applied on 3 set days per week only. Each canister should last 240 days**.**

See BMS information on Testosterone for alternatives if Tostran gel not available

Who can it be prescribed for?

Testosterone can be prescribed for postmenopausal women who complain of loss of sexual desire, which has not responded to oestrogen/progestogen HRT and for which no other cause has been identified. Oestrogen replacement should be optimised first, ensuring an adequate dose of systemic oestrogen with additional vaginal oestrogen if any symptoms of atrophic vaginitis. Changing from oral to transdermal oestrogen may increase free testosterone by reducing SHBG.
Other causes of loss of libido include relationship problems, physical and psychological problems; fatigue, work and family stress, and side effects of medication such as SSRIs.

Testosterone is unlikely to be of benefit to perimenopausal women who are still having periods and **should not be prescribed when there is any risk of pregnancy.**

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How should testosterone gel/cream be used?

The testosterone gel/cream should be 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.

Response to testosterone therapy and duration of use

The loss of sexual desire is complex and may have hormonal, medical, psychosexual and psychosocial aetiologies. In clinical trials of women with HSDD, approximately 2/3 of women responded positively to testosterone therapy (compared to 1/3 using placebo). The trials demonstrated that response may not be immediate, taking 8-12 weeks in some instances for the effect to become clinically significant. It is therefore advised that treatment should trialled for a minimum of 3 months and maximally for 6 months before being discontinued due to lack of efficacy. 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.

What are the possible adverse effects of testosterone therapy?

Response to testosterone with regards to efficacy and adverse effects, is highly variable. However **clinical trials have demonstrated that, if appropriate female physiological doses are prescribed, and adhered to, adverse androgenic effects are not problematic.** However recently updated BMS information recommends that testosterone levels are measured before starting treatment to establish a baseline and to ensure that levels are not at the upper end of the female range, and repeated 2-3 months' later. Unfortunately, there is not the capacity within the Belfast Trust HRT clinic to see and review all patients who request testosterone, nor do we think it necessary to do so. A reasonable plan for prescribing in primary care would be to measure a testosterone level prior to issuing the initial prescription and again 2-3 months later. The timing of the blood sample should ideally be 24-48 hours after an application of gel. If the serum testosterone level is above the upper limit of the normal female range the dose should be reduced to half a pump 3 times per week.

If you would like more information or have any concerns, please do not hesitate to get in touch by contacting the HRT clinic on 02895042899.

We also offer HRT prescribing advice and respond to queries via **CCG Live HRT Clinic Mater Hospital.**

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