Testosterone gel or sachets for the treatment of low sex drive in the menopause

This leaflet will answer some of your questions about the use of testosterone gel or sachets for the treatment of low sex drive in the menopause. If you have any further questions or concerns, please speak to a doctor, nurse or pharmacist caring for you.

What is testosterone?

Testosterone is one of the sex hormones that women produce. Many people think of it as the "male" hormone, but women need to have testosterone too. In fact, women produce three times as much testosterone than oestrogen before the menopause.

Levels of testosterone in your body gradually reduce as you become older and reduce very abruptly in those women who have had an oophorectomy (an operation to have their ovaries removed). Testosterone is also produced by the adrenal glands. It may have a direct action of being used by the body to increase sex drive, or some of it can be converted into oestrogen, which again may help with symptoms.

When a woman's level of testosterone decreases, she may find that she desires sex less often, and when she does have sex, it is not as pleasurable as it used to be, even though she still desires her partner. There is some evidence that having lower testosterone levels can also affect your mood and increase your risk of being depressed.

When you are in the menopause, if you are on hormone replacement therapy (HRT), especially after your ovaries have been removed, you may still have the symptoms of lack of testosterone. These can be low libido, lack of energy, increased tiredness, difficulty concentrating or headaches.

A diagnosis can be made on personal history alone. A blood test is generally not required but may be useful to confirm a diagnosis.

Medicine - taking an unlicensed medicine

At present there are no available testosterone preparations licenced for female use in the UK. Previously available licenced preparations were discontinued for commercial (not medical) reasons. The safety and efficacy of testosterone replacement in women has been demonstrated in randomised studies which have followed women for up to 12 months and reported significant improvement in sexual function.

Due to the lack of availability of licenced female testosterone preparations, products such as Tostran[®] and Testogel[®], which are manufactured and licenced for use in men, have been used outside their product licence to provide female physiological testosterone replacement.

The use of Tostran[®] and Testogel[®] for the treatment of low sex drive is therefore "unlicensed", which means that the manufacturer of the medicine has not specified it can be used in this way. It is not uncommon in clinical practice to use medicines outside their product licence as long as this meets the criteria proposed by the General Medical Council (GMC) and the Government Regulator (The Medicines and Healthcare products Regulatory Agency - MHRA) on prescribing an unlicensed medicine or using a medicine off-label.

What symptoms can testosterone help with?

The National Institute for Health and Care Excellence (NICE) suggests that if women are suffering from menopausal symptoms such as decreased libido, then testosterone may be helpful and can be

tried. This is why the medication is being tried for you now. Testosterone will normally be combined with standard HRTas it works best when there is oestrogen as well.

How is testosterone given?

Testosterone is usually given as a gel to rub into the skin, and there are a couple of different products that might be used. Please note that none of the products are specifically marketed for testosterone replacement in women. They are designed as hormonal replacement therapy in men. Because of this, the instructions for use in the menopause will be different to information contained in the manufacturers' leaflet – it is very important that you follow our instructions and not the manufacturer's leaflet. The desired female testosterone replacement dose is approximately 5 mg a day. This can be provided using Tostran[®] 2% gel, in a pump dispenser, given as one measured pump (which contains 10 milligrams of testosterone) usually used three times a week. Alternatively, Testogel[®] a testosterone product that comes as a gel in a sachet can be used by applying the gel in a sachet usually over the course of 7-10 days (given as a daily dose of a small portion of the pack).

The medicine can take several months to work and it is not effective for every woman. Younger women who have had an early menopause often notice benefits from using testosterone. If you have had your ovaries removed in an operation, then it is very likely that your levels of testosterone will become low very quickly. This is because your ovaries produce the majority of testosterone in your body.

The gel should be applied to clean and dry skin and allowed to dry before you get dressed. You should not have contact with any other person while it is drying (approximately 10-minutes), and you should wash your hands after it has been applied. The area that it is on should not be washed for three hours after application to allow it to be absorbed.

If you find that testosterone is beneficial then you will continue to be prescribed it, alongside your standard HRT.

Is blood test monitoring required?

Blood testing for testosterone is not essential but can be useful. The test is not very sensitive in women. The relief of symptoms and lack of side effects is a more helpful assessment.

What should I do if I forget to take the medicine?

If you miss a dose, take it as soon as you remember. If it is close to the time your next dose is due (within a day) do not take the missed dose and continue with your normal schedule. It is important not to take two dosages of the gel to make up for missing one.

What are the side effects from using testosterone?

There are usually no noticeable side effects of testosterone as it is given to restore testosterone to levels before the menopause. However, some side effects are dose dependent and include:

- hirsutism, increased facial or body hair (common)
- alopecia, male patter hair loss (less common)
- acne and greasy skin (less common)
- deepening of voice (rare)
- enlarged clitoris (rare)

While we have a lot of information about long-term side effects of oestrogen and progesterone replacement therapy in the menopause, there is less information as to any long term effects of testosterone replacement therapy.

Randomised studies have not shown an increased risk of cardiovascular disease or breast cancer with testosterone replacement although longer term follow up studies are lacking. The doctor or nurse looking after you can always discuss your specific risks and benefits from using this if you have any further questions.

Very occasionally, women notice some increased hair growth or skin changes in the area in which they have rubbed the gel. This may be avoided by changing the area of skin on which you rub the gel. Other reported side effects include acne and, if taken in large doses, voice changes.

How do I get a repeat prescription?

Initially your doctor or nurse at the Menopause Clinic will provide your prescription, but when the medication doses and your symptoms are stable, your GP will be able to take over the prescription, and you can get further supplies from your local chemist.

References and further reading:

National Institute for Health and Care Excellence. Menopause: clinical guideline – methods, evidence and recommendations, (NG23), 12 November, Version 1.5, www.nice.org.uk/guidance/ng23/evidence/fullguideline - 559549261 (accessed 6 March 2017).

Hamoda H, Panay N, Arya R et al. The British Menopause Society & Women's Health Concern 2016 recommendations on hormone replacement therapy in menopausal women. Post Reproductive Health 2016; 22(4): 165–183.

The British Menopause Society and Women's Health Concern www.thebms.org.uk; www.womens-health-concern.org

Menopause Matters. <u>www.menopausematters.co.uk</u> (Information on menopause website).

GMC: Good practice in prescribing and managing medicines and devices (2013).

MHRA: Off-label or unlicensed use of medicines: prescribers' responsibilities.