

# Testosterone gel or sachets for women

This leaflet will answer some of your questions about the use of testosterone gel or sachets for symptom management 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. 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 sex drive (libido), lack of energy, increased tiredness, difficulty concentrating or headaches.

#### Why use testosterone?

A low dose of testosterone can sometimes be beneficial at improving your energy, mood, concentration, and sex drive.

### Medicine - taking an unlicensed medicine

At present there are no available testosterone preparations licensed for female use in the UK. Previously available licensed 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 monitored women for up to 12 months and reported significant improvement in sexual function.

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

The use of Tostran<sup>®</sup> and Testogel<sup>®</sup> 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 offlabel.

### 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 sex drive, 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 HRT as it works best when there is oestrogen as well.

## How is testosterone given?

There are no products specifically marketed for testosterone replacement in women in the United Kingdom. They are designed as 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. Testosterone is usually given as a gel to rub into the skin on your lower abdomen or thighs, and there are a couple of different products that might be used. The desired female testosterone replacement dose is approximately 5 mg a day. This can be provided using Testogel® sachet (40.5mg in 2.55g), a testosterone product that comes as a gel. Apply a pea-sized amount from the sachet daily. One sachet should last around 8 days. Alternatively, use Tostran® 2% gel, in a pump dispenser, given as one measured pump (which contains 10 milligrams of testosterone) usually applied three times a week.

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. A 3–6-month trial is usually recommended. At your review appointment, if you find that testosterone is beneficial then you will continue to be prescribed it, alongside your standard HRT.

The gel should be applied to clean and dry skin on either the lower abdomen, buttock or outer thighs and allowed to dry before you get dressed. Rotate the area of skin you apply it to. 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 two to three hours after application to allow it to be absorbed.

#### Is blood test monitoring required?

Blood tests are not able to diagnose whether you need testosterone but are used as a safety check to ensure you are not getting too much on top of your own natural levels. Blood tests before starting might be suggested. 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 (uncommon)
- alopecia (uncommon)
- acne and greasy skin (uncommon)
- 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.

There is a lack of long-term data in using testosterone in women, but data up to five years shows no adverse effect in healthy women after menopause. 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 rotating the area of skin on which you rub the gel or applying as a thinner layer. Other reported side effects include acne and, if taken in large doses, voice changes.

#### How do I get a repeat prescription?

Initially the Menopause Clinic will provide your first prescription. The Clinic will write to your GP practice who will then be able to provide ongoing prescriptions to collect from your local pharmacy.

## References and further reading:

- National Institute for Health and Care Excellence. Menopause: clinical guideline methods, evidence and recommendations, (NG23)
- The British Menopause Society
- Women's Health Concern
- Menopause Matters
- GMC: Good practice in prescribing and managing medicines and devices
- MHRA: Off-label or unlicensed use of medicines: prescribers' responsibilities,

## **Document History**

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