



Patient Information Leaflet Testosterone gel for women experiencing menopausal symptoms

Summary

- Testosterone gel may be helpful for some women in the menopause who experience low sexual desire.
- As testosterone gel is designed for use by men, the instructions for women are different from the information contained in the manufacturer's leaflet. Please see below for more information.
- While testosterone gel is not licensed for use by women, it is considered to be safe and effective.
- At the recommended dose, side effects should be very few.
- It can take several months to work, and is not effective for every woman.
- Regular blood tests are needed to make sure the dose is not too high.

What is testosterone?

You may think of testosterone as a male hormone, but women make this hormone too. It is just one of the sex hormones that women produce, together with the female sex hormones, oestrogen and progesterone.

In women, levels of testosterone in your body gradually reduce as you become older, with many women not even noticing. Others are more sensitive to the changes and sometimes benefit from extra testosterone. Young women who have surgical menopause (removal of ovaries) may notice the change in testosterone more, perhaps because they are younger and because the drop is sudden.

Why use testosterone?

A low dose of testosterone can sometimes be beneficial in improving your sex drive (or libido) when HRT alone is not effective. However, it does not help everyone. Research studies using testosterone in women have not demonstrated the beneficial effects of testosterone therapy for concentration, mood, energy and muscle/bone health.

What symptoms can testosterone help with?

The <u>National Institute for Health and Care Excellence</u> (NICE) suggests that, if women are experiencing low sexual desire related to the menopause, then testosterone may be helpful. This is why your menopause specialist has recommended you try this medication now. Testosterone will normally be combined with standard hormone replacement therapy (HRT) as it works best when there is oestrogen as well.

Can testosterone gel be prescribed for women in Hertfordshire and west Essex?

Yes, the Hertfordshire Medicines Management Committee and west Essex Medicines Optimisation Programme Board have recommended that testosterone gel can be used for women with low sexual desire if HRT alone is not effective. Treatment must be started by a clinician with expertise in treating the menopause. Your GP will be able to refer you to a menopause specialist, who will assess if testosterone gel is suitable.

How is testosterone treatment given?

- Testosterone is usually given as a gel, which you rub into your skin.
- There are three products approved for use in Hertfordshire and west Essex, and your menopause specialist will discuss which is better for you.
- You need to be aware that none of the three products are marketed specifically for testosterone replacement in women. They are designed for hormonal replacement therapy in men. Due to this, the instructions for use in the menopause will be different from the information contained in the





manufacturer's leaflet. It is very important that you follow our instructions, which are outlined below, and not the manufacturer's leaflet.

• The desired female testosterone replacement dose is approximately 5mg a day.

Testogel® comes as a gel in a small sachet and you need to rub only a small amount of this gel into your skin daily. Testogel® was originally available as a 50mg sachet, but this is being discontinued by the manufacturer, and replaced with a 40.5mg sachet. Instructions for use of both strengths are below:

- One 50mg Testogel® sachet should last around 10 days. You should use the 50mg sachet sparingly over 10 days, rolling the top and sealing it with a clip between uses. The amount to apply each day is approximately equal to the size of the tip of a ballpoint pen lid (such as a Biro); your menopause specialist will discuss this with you further. The sachet should be kept in the fridge between uses.
- One 40.5mg Testogel® sachet should last around 8 days. You should use the 40.5mg sachet sparingly over 8 days, rolling the top and sealing it with a clip between uses; your menopause specialist will discuss this with you further. The sachet should be kept in the fridge between uses.

Testim® comes as a gel in a small tube with a screw cap. One 50mg tube should last around 10 days. You should use the tube sparingly over 10 days. The amount to apply each day is approximately equal to the size of the tip of a ballpoint pen lid (such as a Biro); your menopause specialist will discuss this with you further. The tube should be kept in the fridge between uses.

Tostran® comes as a gel in a pump dispenser. The dose is usually one measured pump (which contains 10mg of testosterone) every other day.

How should testosterone gel be used?

The gel should be rubbed onto your lower abdomen or your thighs 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 immediately after the gel has been applied. The area that it is on should not be washed for three hours after application to allow the gel to be absorbed. Your menopause specialist will explain all of this and answer any specific questions you may have.

Taking an unlicensed medicine

- In the UK testosterone is not currently licensed for use by women, so it is said to be prescribed 'off licence'. Your prescriber will explain this to you. It means that the manufacturer cannot advertise or make any recommendations about using the gel for women.
- It is not uncommon in clinical practice to use medicines outside their product licence as long as the use meets the specific requirements of the <u>General Medical Council</u> (GMC) and the government regulator, the <u>Medicines and Healthcare Products Regulatory Agency</u> (MHRA).
- When using a medicine off licence it does not mean that it is unsafe, or that you are part of a clinical trial. Testosterone gel for women has been shown to be effective, and use is supported by expert groups.
- Off licence medicines are only prescribed after careful consideration of other options, and will only be used if it is the most appropriate medicine available.

Are there possible side effects?

If you use the recommended dose, side effects should be very few. This is because testosterone gel is given to restore testosterone to its level before the menopause. However, some side effects are dependent on the dose taken and can include:

increased facial or body hair, known as hirsutism (common)





- male pattern hair loss, known as alopecia (less common)
- acne and greasy skin (less common)
- deepening of voice (rare)
- enlarged clitoris (rare)

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 varying the area of skin on which you rub the gel.

Whilst we have much information about long-term side effects of oestrogen and progesterone replacement therapy in the menopause, there is less information on any long-term effects of testosterone replacement therapy. Randomised studies have not shown an increased risk of cardiovascular (heart) 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 therapy if you have a further question.

How long does it take to work?

The medicine can take several months to work and it is not effective for every woman. Your menopause specialist will therefore prescribe your testosterone gel for the first 3-6 months. If the treatment is working, they will ask your GP to take over prescribing. Your GP will also continue to check that you are responding well, and that you are not experiencing any unwanted side effects.

You may also be advised to use vaginal oestrogen if it is needed to treat vaginal dryness.

Do I need a blood test?

Blood tests cannot diagnose whether or not 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. You will have a blood test before starting, repeated after 3 and 6 months during treatment, and then every 12 months.

Your menopause specialist will carry out your blood tests until your GP takes over your care, which will be 3 to 6 months after you start treatment. Your specialist will let your GP know when your next blood test is due when they ask them to take over prescribing. Please also keep a record of when your tests are due so that you and your GP can work together to make sure your blood tests are done at the right time.

Who should not take testosterone for menopause?

There are some women who should not take testosterone. If you have had hormone sensitive breast cancer or if you have active liver disease, you should not take it.

Looking after your medicine

The instructions on how you should store your medicine will be on the pharmacy label. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the packaging.

Further reading

Adapted from the following sources:

- British Menopause Society toolkit for clinicians: <u>Testosterone replacement in menopause</u> (May 2022)
- Women's Health Concern leaflet: <u>Testosterone for women</u> (February 2022)
- South East London Area Prescribing Committee leaflet: <u>Testosterone gel or sachets for the treatment of low sex drive in the menopause</u> (June 2019)

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