

# **Patient Information and Guidance**

## Testosterone gel for women experiencing menopausal symptoms

## Summary

- Testosterone gel may be helpful for some women who experience low sexual desire during menopause.
- As testosterone gel is designed for use by men, the instructions for women are different from the information contained in the manufacturer's leaflet.
- 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.
- In Norfolk and Waveney, treatment is available in line with national guidance <u>NICE NG23 –</u> <u>Menopause Diagnosis and Management</u> It has been given a classification of ADVICE - GP may initiate testosterone following specialist recommendation. Your GP will contact menopause specialist via Advice and Guidance, and they will assess if this treatment is suitable. If it is, GP will be notified of required preparation, dose and monitoring requirements.
- A 'Specialist' can be defined as a Consultant Endocrinologist / Gynaecologist or a GP with a special interest.

## 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 energy, mood, concentration and also sex drive (or libido). However, it does not help everyone.

## 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 Norfolk and Waveney?

Yes, the Norfolk and Waveney Therapeutics Advisory Group have recommended that testosterone gel can be used for women with low sexual desire if HRT alone is not effective, in line with national guidance. It has been given a classification of **ADVICE - GP may initiate testosterone following specialist recommendation**. Your GP will contact menopause specialist via Advice and Guidance, and they will assess if this treatment is suitable. If it is, GP will be notified of required preparation, dose and monitoring. See **'Appendix 1 – Process'** for more information.

## How is testosterone treatment given?

- Testosterone is usually given as a gel, which you rub into your skin.
- The desired female testosterone replacement dose is approximately 5mg a 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 label'. 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 label, 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 label 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 GP will monitor you closely for the first 3-6 months to ensure that the treatment is working. They will continue to check that you are responding well and 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 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. 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.



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

Your GP will provide your prescriptions following initial recommendation by menopause specialist. You will be able to take your prescriptions to your local pharmacy to obtain your testosterone supply.

#### 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

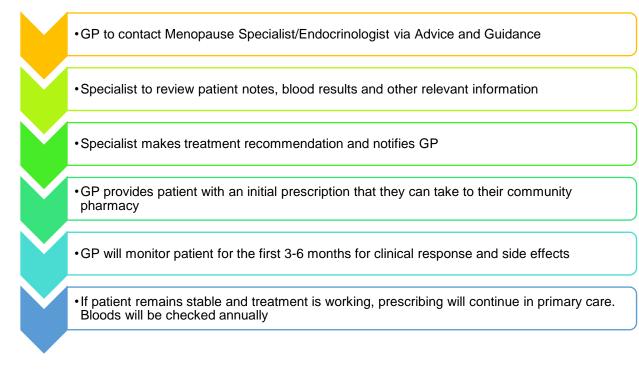
The instructions on how you should store your medicine will be on the pharmacy label. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the packaging.

## **Further reading**

Adapted from document produced by NHS Herts Valleys CCG and NHS East and North Hertfordshire CCG and the following sources:

- British Menopause Society toolkit for clinicians: <u>Testosterone replacement in menopause</u> (accessed Jan 2024)
- Women's Health Concern leaflet: <u>Testosterone for women</u> (February 2022, accessed Jan 2024)
- South East London Area Prescribing Committee leaflet: <u>Testosterone gel or sachets for the treatment of</u> <u>low sex drive in the menopause</u> (June 2019, accessed Jan 2024)

## **Appendix 1 - Process**





Title	Patient Information and Guidance - Testosterone gel for women experiencing menopausal symptoms	
Description of policy	To inform healthcare professionals	
Scope		
Prepared by	Medicines Optimisation Team	
Evidence base / Legislation	Level of Evidence: A. based on national research-based evidence and is considered best evidence <b>B. mix of national and local consensus</b> C. based on local good practice and consensus in the absence of national research based information.	
Dissemination	Is there any reason why any part of this document should not be available on the public website? $\Box$ Yes / No $\boxtimes$	
Approved by	TAG – Feb 2024	
Authorised by	D+TC – Feb 2024	
Review date and by whom	Medicines Optimisation Team – January 2026	
Date of issue	Feb 2024	

Version	Date	Author	Status	Comment
1.0	Feb 2022	TAG Lead Technician	Final	New document to support patients in primary care
1.1	July 2022	As above	Final	Product update
2.0	Jan 2024	As above	Final	Classification amended to ADVICE following TAG discussion
3.0	Oct 2024	As above	Final	Clarify that GP to contact specialist via Advice and Guidance rather than referral process