

## Patient Information Leaflet

### Testosterone gel (Tostran 2%) for low sexual desire in postmenopausal women

#### Introduction

This leaflet provides information about use of testosterone gel Tostran 2%, for postmenopausal women who have a low sexual desire (libido). Testosterone is currently not licensed to women in the UK. The use of this gel is 'off label' which means the manufacturer of the medicine has not applied for a license or has not specified that it can be used in this way. However, it has proven benefits in clinical trials and is also recommended by the [National Institute for Health and Care Excellence](#) (NICE).

#### What is testosterone?

Testosterone is one of the sex hormones produced naturally from ovaries and adrenal glands in women. It is commonly thought of as a male hormone, but testosterone plays an important role in a women's life including desire for sex. Levels of testosterone gradually go down as women get older. Young women who have surgical menopause (removal of ovaries) may notice the change in testosterone more.

When a woman's level of testosterone decreases, it could lead to distressing sexual symptoms such as low sexual desire. There is some evidence that having lower testosterone levels can also affect your mood and increase your risk of being depressed.

#### What are the potential benefits of testosterone gel?

Testosterone may improve libido, mood, energy, and concentration. Low libido may improve with oestrogen therapy alone, but in some cases testosterone may be more helpful, especially in women who have had their ovaries removed. According to the [National Institute for Health and Care Excellence](#) guidelines on menopause management, use of testosterone for women who are already taking hormone replacement therapy (HRT) may be helpful. It will often take three to four months to determine whether testosterone will be effective. There is insufficient evidence to support the use of testosterone supplements to enhance wellbeing, mood, cognitive function, energy levels or musculoskeletal health.

#### Can testosterone gel be prescribed for women in Cambridgeshire and Peterborough?

Yes, 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 gel used?

Tostran 2% testosterone gel comes in a canister. Pressing the pump once releases a pea sized amount equal to a 10mg dose which needs to be applied on alternate days.

The gel should be rubbed onto clean dry skin (lower abdomen or upper thighs). The area should be allowed to dry before getting dressed and should not be washed for 2 to 3 hours

after applying the gel. You should keep changing the area where you apply the gel to avoid hair growth in that area. Hands should be washed immediately after applying the gel to the body.

The area of your skin should not come into contact with partners, children and pregnant women. Take care that the testosterone product is not accidentally transferred onto the skin of someone else as this can lead to increased blood testosterone levels in the other person which may result in side effects (facial and body hair growth, deepening of voice and changes in the menstrual cycle of women, or accelerate height, genital enlargement, and early puberty including development of public hair in children). Please take the following precautions to reduce the risk of accidentally transferring testosterone from your skin to another person:

- After applying the product, wash your hands with soap and water.
- Once the product has dried, cover the application site with clean clothing.
- Before physical contact with another person (adult or child), wash the application site with soap and water.

**DO NOT use the amounts stated in the medicine packet leaflet as this is how much a man should use. It is very important that you follow the instructions for use and dosage of your specialist and doctor and not the manufacturer's leaflet.**

#### What are the side effects?

Studies have shown that if you follow the instructions carefully, most people can benefit from testosterone gel. Possible side effects are:

- increased facial or body hair, known as hirsutism – uncommon
- male pattern hair loss known as alopecia – uncommon
- acne and greasy skin – uncommon
- 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 any further questions.

#### 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 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.

#### Is blood test monitoring required?

Blood tests are not able to 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. Blood tests will be carried out before starting and repeated after 3 months on treatment then once every year. If you find that testosterone is helpful, then you would normally continue to use this while you are taking the standard HRT.

#### When should testosterone gel not be used?

Testosterone should be avoided or used in caution:

- if you have active liver disease
- if you have a history of hormone sensitive breast cancer
- if you are a competitive athlete
- for women who have a high baseline Free Androgen Index (FAI)

#### Further Information

The British Menopause Society: [www.thebms.org.uk](http://www.thebms.org.uk)

Women's Health Concern: [www.womens-health-concern.org](http://www.womens-health-concern.org)

#### Document ratification details

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