

# PATIENT INFORMATION LEAFLET

## ☒ TESTOSTERONE CREAM

Read this entire leaflet carefully because it contains important information for you.

**This product is available on a doctor's prescription only,** and you need to use Testosterone Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your medical practitioner or pharmacist if you need more information or advice.
- You need to see your medical practitioner or pharmacist if your symptoms worsen or do not improve after 30 days.

### Scheduling status:

To be determined (Testosterone is listed as a schedule 5 substance).

### Proprietary name and dosage Form:

Testosterone Cream 50ml.

### Composition:

Each 1ml level scoop of Testosterone Cream contains 2.5mg (0.25%), 5mg (0.5%), 25mg (2.5%) or 50mg (5%) of Testosterone Cream, in a liposomal, non-petrochemical, xenoestrogen-free transdermal lecithin base for improved systemic absorption.

### Pharmacological Classification:

A.32.16 Others.

### Pharmacological action:

Testosterone is primarily secreted in the testes of men and the ovaries of women, but is also made in smaller amounts by the adrenal glands in both men and woman. Testosterone plays a key role in health and well-being, as well as in sexual functioning in both men and women.

**Men:** As a man ages, his testosterone level begins to decrease, many times falling below normal levels. Common symptoms of low testosterone levels include: fatigue or tiredness, loss of muscle mass and muscle strength, low sex drive, erectile dysfunction, depression, moodiness, sadness, low self-esteem, brittle bones and increased blood sugar levels.

**Women:** Women also need testosterone. Women have about 10% of the testosterone level of men. When a woman goes through menopause, her testosterone levels can decline dramatically. Women who have low levels of testosterone may experience a decrease in sex drive, lower energy levels and decrease in muscle and bone structure.

### Indications:

Testosterone is used topically as a component of hormone replacement therapy.

### Contra-indications:

Hypersensitivity to any of the ingredients.

### Warnings:

Not to be used by pregnant or breast-feeding women. Not to be used by individuals under the age of 18, unless under the supervision of a medical practitioner. Testosterone may cause acne or minor facial hair that will go away if the dosage is lowered or if the cream is used less often. Testosterone may have a stimulating effect, it is therefore advisable to use in the mornings and afternoons before 4pm. Cover the area of application with clothing after application if you are in direct skin-to-skin contact with children, other people or animals until the cream is absorbed.

Do not exceed recommended dosages unless on the

advice of a medical practitioner. If you are on any medication or suffering from any medical condition, it is advisable to seek medical advice before beginning any new medicine, supplement or remedy.

### Interactions:

There are no known interactions with natural Testosterone Cream at recommended dosages, as it is a bio-identical hormone which already exists in your body.

### Pregnancy and breast-feeding:

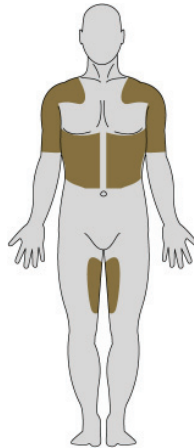
Not to be used by pregnant or breast-feeding women.



### Dosage and directions for use:

Testosterone Cream must be applied topically.

**MEN:** If you are not obtaining the desired results please consult with your medical practitioner as you may require an adjustment in the dosage you are using. Apply 1ml level scoop of 2.5% or 5% Testosterone Cream, to the skin once or twice daily or as directed by your medical practitioner.



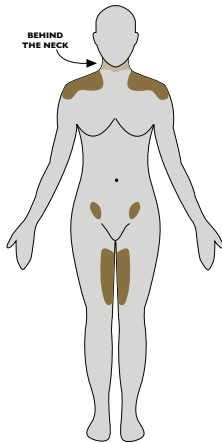
### MEN: Directions for application of the cream:

- Testosterone Cream should be applied at the same time every day, preferably in the morning (or as directed by your medical practitioner), to clean, dry, intact skin.
- Area of application must be washed with hot water and patted dry before application. Ensure that area is completely dry before you apply the cream.
- Do not apply any other creams to this area before applying the Testosterone Cream.
- Apply and rub the cream to one or more of the application sites as per the illustration. Rub the cream into your skin, until it disappears.
- Apply on large skin surfaces.
- Apply to lean muscle not to fatty tissue.
- Apply to a non-hairy area, as the enzyme that converts testosterone to estrogen is found in fatty tissue and on hair follicles.

- Rotate sites to avoid saturation.
- After application wash hands with soap and water.
- Allow the application sites to dry before getting dressed.
- Do not bath for two hours after application.
- Do not exercise for two hours after application.
- Avoid direct skin-to-skin contact with children, other people or animals until cream is absorbed.
- Do not apply to the genital area.



**WOMEN:** If you are not obtaining the desired results please consult with your medical practitioner as you may require an adjustment in the dosage you are using. Apply 1ml level scoop of 0.25% or 0.5% Testosterone Cream, to the skin once or twice daily or as directed by your medical practitioner.



**WOMEN: Directions for application of the cream:**

- Testosterone Cream should be applied at the same time every day, preferably in the morning (or as directed by your medical practitioner), to clean, dry, intact skin.
- Area of application must be washed with hot water and patted dry before application. Ensure that area is completely dry before you apply the cream.
- Do not apply any other creams to this area before applying the Testosterone Cream.
- Apply and rub the cream to one or more of the application sites as per the illustration. Rub the cream into your skin, until it disappears.
- Apply on large skin surfaces.
- Apply to a non hairy area.
- Rotate sites to avoid saturation.
- After application wash hands with soap and water.
- Allow the application sites to dry before getting dressed.
- Do not bath for two hours after application.
- Do not exercise for two hours after application.
- Avoid direct skin-to-skin contact with children, other people or animals until cream is absorbed.
- Do not apply to the breasts. Can be use vaginally, but only if prescribed as such by a medical practitioner.

**Side-effects and special precautions:**

Minor side effects such as acne and oily skin may occur. It is recommended that men have their PSA (prostate-specific antigen) and hemoglobin levels taken and tested for prostate cancer before using testosterone. Base contains ingredients

which can cause local skin redness or itching in 1-2% of users.

**Known symptoms of overdosage and particulars of its treatment:**

See side-effects and special precautions. Treatment is symptomatic and supportive.

**Storage Instructions:**

Store in a cool (below 25°C), dry place. Protect from moisture. Keep container tightly closed. Keep out of reach of children.

**Presentation:**

Plastic tub (50ml) with screw-on lid. Supplied with a 1ml plastic scoop.

**Identification:**

Soft yellow cream.

**Registry Number:**

Testosterone Cream 0.25%: 001570  
 Testosterone Cream 0.5%: 001578  
 Testosterone Cream 2.5%: 001573  
 Testosterone Cream 5%: 001569

**Name and Business Address of Applicant:**

Solal Technologies Fine Pharmaceuticals (Pty) Ltd  
 PO Box 782484, Sandton, 2146, South Africa

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April 2009



**PRESCRIBED BY DOCTORS  
 RECOMMENDED BY PHARMACISTS™**

**SOLAL Technologies**

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