

Package leaflet: Information for the user
Tostran® 2% Gel
(testosterone)

This product is available by the above name but will be referred to as Tostran throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, See section 4.

What is in this leaflet

1. What Tostran is and what it is used for
2. What you need to know before you use Tostran
3. How to use Tostran
4. Possible side effects
5. How to store Tostran
6. Contents of the pack and other information

1. What Tostran is and what it is used for

The active substance, testosterone, is a male hormone, which is a type of androgen.

Tostran is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as:

- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone levels

2. What you need to know before you use Trostan

Tostran must only be used if hypogonadism has been confirmed by your doctor, based on your symptoms and laboratory tests. Other reasons for your symptoms must have been excluded by your doctor prior to the start of treatment.

Only men can use Tostran. Tostran has not been tested in males less than 18 years of age, and there is limited experience of treating men older than 65 years of age.

Do not use Tostran:

If you:

- are allergic to testosterone or to any of the other ingredients of this medicine (listed in section 6.)
 - have or are suspected of having cancer of the breast or prostate
- If any of these applies to you, tell your doctor or pharmacist.

Warnings and precautions:

A check-up is necessary before you begin treatment, and periodically during treatment (usually once or twice a year).

If you are suffering from severe heart, liver or kidney disease, treatment with Tostran may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.

Testosterone treatment may increase the risk of development of an enlarged prostate gland (benign prostatic hyperplasia) or prostate cancer. Testosterone treatment may also affect the number of red blood cells you have, your blood fat profile and your liver function.

Tell your doctor before treatment if you:

- have swollen hands and feet
 - are overweight or suffer from a chronic lung disease, as testosterone treatment may worsen sleep apnoea (temporary cessation of breathing during sleep)
 - have diabetes and use insulin to control your blood sugar levels, as testosterone treatment may affect your response to insulin
 - have or develop epilepsy or migraines, as these conditions may get worse during treatment
 - suffer from skeletal cancer, as your doctor will have to monitor your blood calcium levels during treatment
 - have or have ever had blood clotting problems
 - thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis - blood clots in blood vessels)
 - have factors that increase your risk of blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or organ at a young age (e.g. below the age of about 50); or as you get older.
- How to recognise a blood clot: painful swelling in one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain, severe lightheadedness or dizziness, severe pain in your stomach, sudden loss of vision. Seek urgent medical attention if you experience one of these symptoms.

Contact your doctor if you:

- have frequently-occurring or persistent erections
- feel irritable, nervous, or notice weight gain
- feel nauseous, vomit, notice changes in your skin colour or your ankle joints become swollen

- notice any changes in breathing patterns including during sleep

These symptoms may mean that your dose of Tostran is too high, and your doctor may need to adjust your dose.

Contact your doctor if you notice any skin reactions at the site of application such as burning or prickling sensation, dryness, rash, redness or itchiness. If the reaction is severe, treatment should be reviewed by your doctor and stopped if necessary.

If you are an athlete please note that Tostran contains testosterone, which may give positive results in a doping test.

Tostran should not be used to treat male sterility or sexual impotence.

Tostran should not be used by women due to possible virilising effects (such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle).

How to prevent transfer of Tostran to someone else:

During repeated or prolonged periods of physical contact, this medicine may be transferred to another person. This may cause side-effects such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle of women or accelerated height, genital enlargement, and early puberty (including development of pubic hair) in children. Wearing clothes covering the application area or washing the application area before contact may reduce this risk.

Additional care should be taken by patients using this product who may be in close physical contact with children as testosterone may pass through clothing. Please make sure you follow the application technique (see section 3 of this leaflet) when in physical contact with children, including covering the application site with clean clothing once the gel has dried. Additionally, please wash the application site with soap once the recommended time period (at least 2 hours) has passed and cover again with clean clothing before physical contact with children.

In order to guarantee the safety of your partner you should wait for at least four hours after application of Tostran before having sexual intercourse and wear clothing which covers the application site at the time of contact or wash the site of application with soap and water before sexual intercourse.

You should wear clothing which covers the application site when in contact with children, in order to avoid the risk of transferring the gel to the child's skin.

If you transfer some of the testosterone gel to another person by skin-to-skin contact, or someone else is exposed by direct contact with the gel itself, wash the contact area of the other person with soap and water as soon as possible.

If Tostran is applied to a patient by a health care professional or carer, they should wear suitable disposable gloves. The gloves should be resistant to alcohol as the gel contains ethanol and isopropyl alcohol.

Contact your doctor if you notice changes in body hair, significantly increased acne or other signs of development of male characteristics in **people not being treated with Tostran (i.e., female partner or children)**.

Other medicines and Tostran:

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, especially the following:

- Anticoagulants
- corticosteroids

Also tell your doctor or pharmacist about any medicines that you may have bought for yourself without prescription.

Tostran with food and drink:

Tostran is not affected by your intake of food or drink.

Pregnancy and breast-feeding

- Tostran is only intended to be used by men.
- Tostran must not be used by pregnant or breastfeeding women.
- Pregnant women should avoid all contact with skin treated with Tostran. Tostran may cause harm or abnormalities in the unborn baby. If your partner becomes pregnant, you **must** follow the advice regarding avoiding transfer of the testosterone gel given in this section. In the event of contact with treated skin, the area should be washed immediately with soap and water.

Driving and using machines:

Tostran is unlikely to have an effect on your ability to drive and use machines.

Tostran contains butylhydroxytoluene, propylene glycol and ethanol

Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.

This medicine contains 175 mg propylene glycol in each pump depression.

This medicine contains 75 mg alcohol (ethanol) in each pump depression. It may cause burning sensation on damaged skin.

This product is flammable until dry.

3. How to use Tostran

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure about how and when to apply the gel.

The usual starting dose is 3 g of gel (containing 60mg of testosterone) per day. The dose may be adjusted by your doctor, and the maximum dose is 4 g of gel (80 mg of testosterone) per day.

Tostran is supplied in a canister with a pumping mechanism which delivers one half gram of gel (10 mg of testosterone) each time the piston is depressed (when the pump mechanism is pushed right down).