PACKAGE LEAFLET: INFORMATION FOR THE USER

Tostrex 20 mg/g transdermal gel
Testosterone

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 TOSTREX IS AND WHAT IT IS USED FOR

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

Tostrex 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 TOSTREX

Tostrex 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 Tostrex. Tostrex 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 Tostrex:
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 Tostrex 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 Tostrex 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 Tostrex contains testosterone, which may give positive results in a doping test.

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

Tostrex 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 Tostrex 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 Tostrex 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 Tostrex 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 Tostrex (i.e., female partner or children).**

Other medicines and Tostrex:
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, especially the following:
- anticoagulants
- corticosteroids
- medicines used to treat diabetes. It may be necessary to adjust the dose of your blood sugar reducing medicine. Like other androgens, testosterone may increase the effect of insulin. Taking SGLT-2 inhibitors (such as empagliflozin, dapagliflozin or canagliflozin) together with testosterone may increase the number of red blood cells in your blood. Your doctor may need to monitor your blood more regularly.

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

Tostrex with food and drink:
Tostrex is not affected by your intake of food or drink.

Pregnancy and breast-feeding

- Tostrex is only intended to be used by men.
- Tostrex must not be used by pregnant or breastfeeding women.
- Pregnant women should avoid all contact with skin treated with Tostrex. Tostrex 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:
Tostrex is unlikely to have an effect on your ability to drive and use machines.

Tostrex 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 TOSTREX

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.

Tostrex 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).

Using the canister for the first time:
Before you use the dosing pump for the first time it must be primed. To do so, with the canister in the upright position, slowly and fully depress the actuator repeatedly until gel appears. Depress the actuator a further 6 times. Discard the gel from the six depressions. It is only necessary to prime the pump before the first dose.

Administration of Tostrex:
Your doctor will tell you how many depressions of the piston to make to get the correct dose of gel for you once the pump has been primed. The table below gives you more information on this.

Number of Depressions	**Amount of Gel (g)**	**Quantity of Testosterone Applied to the Skin (mg)**
1	0.5	10
2	1	20
4	2	40
6	3	60
8	4	80

Apply the gel onto clean, dry intact skin, once a day at the same time each day, for example in the morning after showering.

The gel should either be rubbed onto the abdomen (over an area of at least 10 by 30 cm) or divided in half and one half rubbed onto the inside of **each** thigh (over an area of at least 10 by 15 cm). It is recommended that you rub Tostrex onto your abdomen and **both** your inner thighs on alternate days.

Application to other sites should be avoided. Tostrex must not be applied to the genitals..

Rub the gel in gently with one finger until dry. Once the gel has dried wear clothing that covers the application site at all times to prevent accidental transfer to other persons as well as pets. When finished, wash your hands thoroughly with soap and water. Before close physical contact with another person (adult or child) or pets, wash the application site with soap and water once the recommended time period (at least two hours) has passed and cover again with clean clothing.

If you are thinking of taking a shower or bath, do so either before application of Tostrex or wait for at least two hours after the application.

Two weeks after beginning to use your medicine your doctor will take blood samples to see if your dose needs to be changed. Whilst you are taking Tostrex, you should expect to have regular medical follow-up.

If you are arranging for testing of blood samples while using Tostrex you must ensure that all testosterone measurements are performed in the same laboratory, because of the variability in analytical values among diagnostic laboratories.

If you use more Tostrex than you should:
If you have applied too much Tostrex, contact a doctor, hospital or pharmacist.

If you forget to use Tostrex:
Do not take a double dose to make up for forgotten individual doses. Apply the next dose at the usual time.

If you stop using Tostrex:
Always talk to your doctor or pharmacist before stopping using Tostrex.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects *(affects more than 1 user in 10)* are skin reactions at the site of application such as burning or prickling sensation, dryness, rash, redness or itchiness. These are usually mild transient side effects of Tostrex but if they are troublesome or last for more than a few days, talk to your doctor or pharmacist as soon as possible.

Common side effects *(affects 1 to 10 users in 100)* are: swelling of hands or feet, high blood pressure, prostate changes (including: increased blood levels of a protein called prostate specific antigen that is produced by the prostate), increased body hair growth, increase in breast size, increased number of red blood cells (measured in blood samples). Increase in red blood cell count, haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests.

Other known undesirable effects associated with testosterone treatments include: baldness, seborrhoea, acne, jaundice (liver problems which sometimes may be associated with yellowing of the skin and the whites of the eyes), abnormal liver function tests, nausea, changes in libido, increased frequency of erections, difficulty in passing urine, depression, nervousness, hostility, weight gain, muscle cramps or pain, fluid retention, swelling of ankles, sleep apnoea, and rare cases of painful and persistent erections. A reduction in sperm production and the size of the testicles may occur at high doses. Prolonged testosterone administration may cause changes in the levels of salts (electrolytes) in the body.

There is no convincing evidence that testosterone replacement in hypogonadal men induces prostate cancer. However, testosterone therapy is to be avoided in men already known or thought to have prostate cancer.

Hyperglycaemia (too much sugar in the bloodstream) has been reported in the case of 2 people with a history of diabetes mellitus.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOSTREX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the canister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze.

Once opened store canister upright.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tostrex contains
- The active substance is testosterone. One gram of gel contains 20 mg of testosterone.
- The other ingredients are propylene glycol; ethanol, anhydrous; isopropyl alcohol; oleic acid; carbomer 1382; trolamine; butylhydroxytoluene (E321); water, purified and hydrochloric acid (for pH adjustment).

What Tostrex looks like and contents of the pack
Tostrex is a clear gel, which varies from colourless to slightly yellow in appearance.

Tostrex comes in canisters each containing 60 grams of gel. The canisters have a pumping mechanism, which delivers a fixed amount of gel.

A carton may contain one, two or three canisters of gel. Not all pack sizes may be available.

Marketing Authorisation Holder:
[To be completed nationally]

Manufacturer:
PHARBIL Waltrop GmbH
Im Wirrigen 25
45731 Waltrop
Germany

This medicinal product is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Cyprus, Denmark, Finland, Germany, Greece, Ireland, Netherlands, Norway, United Kingdom (and Northern Ireland): Tostran

Italy, Sweden: Tostrex

Spain: Itnogen

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