

Prescribing Information
Tostran® (testosterone) 2% Gel

Please refer to the full Summary of Product Characteristics before prescribing

Presentation: Tostran 2% Gel, contains testosterone, 20 mg/g. **Indication:** Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Dose:** The recommended starting dose is 3 g gel (60 mg testosterone) applied once daily to clean, dry, intact skin, on the abdomen or to both inner thighs. Dose titration should be based on both serum testosterone levels and the existence of clinical signs and symptoms related to androgen deficiency. Do not exceed 4 g of gel (80 mg testosterone) daily. Apply after washing, bathing or showering. Do not apply to the genitals. Do not use in women, or children under the age of 18 years. **Contraindications:** Known or suspected carcinoma of the breast or the prostate; hypersensitivity to any of the ingredients. **Special warnings and precautions for use:** Not to be used to treat non-specific symptoms suggestive of hypogonadism if testosterone deficiency has not been demonstrated and if other aetiologies have not been excluded. Oedema with/without congestive heart failure may be a severe complication in patients with pre-existing severe cardiac, renal, or hepatic insufficiency, or ischaemic heart disease; discontinue immediately if such complications occur. May cause rise in blood pressure; use in caution in hypertension. Monitor testosterone at baseline and regular intervals. Adjust dose to maintain eugonadal testosterone level. In long-term use, regularly monitor: haemoglobin, and haematocrit, liver function tests and lipid profile. Experience in patients over 65 years is limited; account for lower serum testosterone with increasing age. Not indicated for treatment of male sterility or impotence. Not indicated in women due to possible virilising effects. Androgens may accelerate the development of subclinical prostatic cancer and benign prostatic hyperplasia. Pre-examine all patients to exclude a risk of pre-existing prostatic cancer. Perform regular monitoring of breast and prostate, at least annually and twice yearly in the elderly and at-risk patients. Sleep apnoea may be potentiated by testosterone treatment, especially in obesity or chronic lung disease. Use with caution in renal or hepatic impairment. Use with caution in thrombophilia or risk factors for venous thromboembolism (VTE). Reports of thromboembolism, even in thrombophilic patients under anticoagulation therapy have been received, therefore careful evaluation of continued testosterone therapy recommended after first event, with further measures to minimise individual VTE risk. Use with caution in epilepsy and migraine as these conditions may be aggravated. Take care in skeletal metastases; monitor calcium regularly due to risk of hypercalcaemia/hypercalciuria. Androgen treatment may result in improved insulin sensitivity. Inform the patient on the risk of testosterone transfer and give the safety instructions as specified in the Tostran SmPC. Health professionals/carers should use disposable gloves resistant to alcohols. **Interactions :** Effects of anticoagulants can increase; monitor INR closely on testosterone initiation and at dose change. On concurrent administration with ACTH or corticosteroids likelihood of oedema may increase; administer with caution particularly in cardiac, renal or hepatic disease. In the laboratory, testosterone can decrease thyroxin-binding globulin; however, free thyroid hormone concentrations remain unchanged. **Side-effects:** *Very common:* Application site reactions (including paraesthesia, xerosis, pruritis, rash or erythema). *Common:* Increased haemoglobin, red blood cell count, and haematocrit. Increased male pattern hair distribution. Hypertension, gynaecomastia, peripheral oedema, and increased PSA. May cause irritation and dry skin. Tostran contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes. Prescribers should consult the summary of product characteristics for further details of side effects. **Overdose:** Oral ingestion of Tostran will not result in clinically significant testosterone concentrations due to extensive first-pass metabolism. It is unlikely that such serum testosterone levels could be achieved using the transdermal route of administration. Treatment of transdermal overdosage is by washing the site of application with soap and water as soon as possible, discontinuing application of Tostran and treatment of any symptoms. **Legal Category:** POM. **Pack Size and Price:** Pack contains one 60 g metered-dose canister. **Basic price: £28.63. Marketing Authorisation Holder:** ADVANZ PHARMA Limited, Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland **Marketing Authorisation Number:** PL 56734/0010. **Last revised:** April 2024.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> Adverse events should also be reported to **Advanz Pharma Medical Information** via telephone on +44 (0) 208 588 9131 via e-mail at medicalinformation@advanzpharma.com