

Tostran® (testosterone) 2% Gel Prescribing Information

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 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. Adjust dose according to clinical and laboratory responses. 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. Not indicated for treatment of male sterility or impotence. Monitor testosterone at regular intervals. Adjust dose to maintain eugonadal testosterone level. Experience in patients over 65 years is limited; account for lower serum testosterone with increasing age. Pre-examine all patients to exclude a risk of pre-existing prostatic cancer. Perform regular monitoring of breast and prostate. Androgens may accelerate the development of subclinical prostatic cancer and benign prostatic hyperplasia. Use with caution in thrombophilia due to risk of thrombosis. Monitor haemoglobin, and haematocrit, liver function tests and lipid profile during long-term use. 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. Use with caution in hypertension, epilepsy, migraine and sleep apnoea as these

conditions may be aggravated. Care should be taken with skeletal metastases due to risk of hypercalcaemia/hypercalciuria. Androgen treatment may result in improved insulin sensitivity. Inform the patient about the risk of testosterone transfer and give safety instructions. Health professionals/carers should use disposable gloves resistant to alcohols. **Side-effects:** *Very common:* Application site reactions (including paresthesia, 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. Prescribers should consult the summary of product characteristics for further details of side effects. **Legal Category:** POM. **Further Information is available from the Marketing Authorisation Holder:** Kyowa Kirin Ltd, Galabank Business Park, Galashiels, TD1 1QH, UK. **Date of Prescribing Information:** March 2017.

For the United Kingdom: Pack Size and Price: Pack contains one 60 g metered-dose canister. Price £28.67. **Marketing Authorisation Number:** PL16508/0025.

Adverse Events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Kyowa Kirin Ltd on +44 (0)1896 664000, email medinfo@kyowakirin.com

References: 1. Tostran 2% Gel SPC, 2. eMIMS October 2018

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KYOWA KIRIN

