ANDROTAS

ANDROTAS Testosterone Gel 1% w/w Composition: Each g contains: Testosterone USP 10 mg Ethanol IP 67.0% w/w Gel base Q.S. Indication Androtas is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: • Primary hypogonadism (congenital or acquired):Testicular failure due to conditions such as cryptorchidism,bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins {Follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. • Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range. Limitations of use: •Safely and efficacy of Androtas in men with 'age-related hypogonadism' ('late-onset hypogonadism') have not been established. Safety and efficacy of Androtas in males less than 18 years old have not been established. •Topical testosterone products may have different doses, strengths or application instructions that may result in different systemic exposure. Dosage and administration: Cutaneous use. Adult and Elderly men: The recommended dose is 5g of gel (i.e. 50 mg of testosterone (4 pump actuations, one 50 mg packet) applied once daily at about the same time, preferably in the morning. The daily dose should be adjusted by the doctor depending on the clinical or laboratory response in individual patients, not exceeding 10g of gel per day. Androtas should be applied to clean, dry, healthy, intact skin of the right and left upper arms/shoulders and/or right and left abdomen. Area of application should be limited to the area that will be covered by the patient's short sleeve T-shirt. Do not apply Androtas to any other part of the body including the genitals, chest, armpits (axillae), knees, or back. Androtas should be evenly distributed between the right and left upper arms/shoulders or both sides of the abdomen. To obtain a full first dose, it is necessary to prime the canister pump. To do so, with the canister in the upright position, slowly and fully depress the actuator three limes. Safely discard the gel from the first three actuations. It is only necessary to prime the pump before the first dose. After the priming procedure, patients should completely depress the pump one time actuation for every 12.5 mg of testosterone required to achieve the daily prescribed dosage.

Dosing Information for Androtas gel 1%

Amount of Testosterone	Number of Pump Actuations
50 mg	4 (once daily)
75 mg	6 (once daily)
100 mg	8 (once daily)

After applying the gel, the application site should be allowed to dry prior to dressing. Hands should be washed thoroughly with soap and water after application. Avoid fire, flames or smoking until the gel has dried since alcohol based products, including Androtas, are flammable. The patient should be advised to avoid swimming or showering for at least 5 hours after the application of Androtas. Steady state plasma testosterone concentrations are reached approximately on the 2nd day of treatment by testosterone gel. In order to adjust the testosterone dose, serum testosterone concentrations must be measured in the morning before application, approximately 7 days after initiation of therapy.The dose may be reduced if the plasma testosterone concentrations are raised above the desired level. If the concentrations are low, the dosage may be increased, not exceeding 10 g of gel per day. Contraindications: •In cases of known or suspected prostatic cancer or breast carcinoma, • In cases of known hypersensitivity to the active substance or any of the excipient. Most common adverse reactions are acne, application site reaction, abnormal lab tests, and prostatic disorders. Warnings and precautions: Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH. Avoid unintentional exposure of women or children to Androtas gel. Secondary exposure to testosterone can produce signs of virilization. It should be discontinued. Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported. Some post marketing studies have shown an increased risk of myocardial infarction and stroke associated with use of testosterone replacement therapy. Exogenous administration of androgens may lead to azoospermia. Edema, with or without congestive heart failure (CHF), may be a complication in patients with preexisting cardiac, renal, or hepatic disease. Sleep apnea may occur in those with risk factors. Monitor serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver function tests, and lipid concentrations periodically. Androtas 1% is flammable until dry. There is limited experience on the safety and efficacy of the use of Testosterone gel 1% in patients over 65 years of age. Testosterone gel 1% w/w should not be used by women, due to possibly virilizing effects. Gynecomastia may develop and persist in patients being treated with androgens, including Androtas, for hypogonadism.Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dosage adjustment. Gynecomastia may develop and persist in patients being treated with androgens, including Androtas, for hypogonadism. It should be used with caution in patients with epilepsy and migraine as these conditions may be aggravated. Precautions should be taken, to avoid transfer of testosterone gel to other persons. Avoid unintentional exposure of women or children to Androtas.Secondary exposure to testosterone can produce signs of virilization. Pregnancy & lactation: Androtas is contraindicated during pregnancy or in women who may become pregnant. Testosterone is teratogenic and may cause fetal harm. Exposure of a female fetus to androgens may result in varying degrees of virilization. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. Pregnant women must avoid any contact with Testosterone gel (1%w/w) application sites. This product may have adverse virilizing effects on the foetus. In the event of contact, wash with soap and water as soon as possible. Androtas is contraindicated in nursing women because of the potential for serious adverse reactions in nursing infants.Testosterone and other androgens may adversely affect lactation. Adverse drug reactions: skin reactions : reaction at the application site, erythema, acne, dry skin. Increased PSA, Increased haematocrit, Increased haemoglobin , Increased red blood cell count ,headache, acne. Other adverse reactions: Gynecomastia, Pruritus, Hot flushes/flushing.

(For the use of a registered medical practitioner or hospital or laboratory only)