

הנדון: עדכון העלון לרופא לתכשירים Testomax 25 mg & Testomax 50 mg

חברת פאדאגיס ישראל פרמצבטיקה בע"מ מבקשת ליידע אתכם על עדכון העלון לרופא של התכשירים:

<i>שם תכשיר:</i>	<i>טסטומקס 25 מ"ג Testomax 25mg</i>
<i>ו-</i>	<i>טסטומקס 50 מ"ג Testomax 50 mg</i>
<i>חומר פעיל:</i>	<i>Testosterone 25mg/2.5 g sachet</i>
<i>ו-</i>	<i>Testosterone 50mg/5 g sachet</i>
<i>התוויה:</i>	<i>Testosterone replacement therapy for males hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.</i>

עדכון זה מכיל החמרות המפורטות בהודעה זו על גבי רקע זהוב.
העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לצפות בו במלואו
בכתובת הבאה: <https://israeldrugs.health.gov.il/#!/byDrug>
כמו כן, ניתן לפנות לחברת פאדאגיס לפרטים נוספים באתר החברה: Padagis.co.il דרך "צור קשר".

בברכה,
פאדאגיס ישראל פרמצבטיקה בע"מ

פירוט העדכונים המהותיים:

4.4 Special warnings and precautions for use

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Testosterone should be used with caution in patients with thrombophilia **or risk factors for venous thromboembolism (VTE)**, as there have been post-marketing studies and reports of thrombotic events (e.g. deep-vein thrombosis, pulmonary embolism, ocular thrombosis) in these patients during testosterone therapy. **In thrombophilic patients, VTE cases have been reported even under anticoagulation treatment, therefore continuing testosterone treatment after first thrombotic event should be carefully evaluated. In case of treatment continuation, further measures should be taken to minimise the individual VTE risk.**

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Improved insulin sensitivity may be observed in patients treated with androgens and may require a decrease in the dose of antidiabetic medications (see section 4.5). Monitoring of the glucose level and HbA1c is advised for patients treated with androgens.

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This medicine contains approximately 1.68 mg alcohol in each 2.5 g sachet, and 3.35 mg alcohol in each 5 g sachet. It may cause burning sensation on damaged skin.

This product is flammable until dry.

4.5 Interaction with other medicinal products and other forms of interaction

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Diabetic medication

Improved insulin sensitivity, glucose tolerance, glycaemic control, blood glucose and glycosylated haemoglobin levels have been reported with androgens. In diabetic patients, the dose of antidiabetic medications may need reduction (see section 4.4).

4.6 Fertility, Pregnancy and Lactation

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Fertility

Spermatogenesis may be reversibly suppressed with this medicine.

4.8 Undesirable effects

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Investigations

Common ($\geq 1/100$; $< 1/10$):

Haematocrit increased, haemoglobin increased, red blood cell count increased

Very rare ($< 1/10,000$):

Liver function test abnormalities

4.9 Overdose

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Symptoms

Serum testosterone levels should be measured if clinical signs and symptoms indicative of over exposure to androgen are observed. Application site rash has also been reported in case reports of overdose with this medicine.

Treatment

Treatment of over dosage consists of washing the application site immediately and discontinuing treatment if advised by the treating physician.