11.2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

Mounjaro 2.5/ 5/ 7.5/ 10/ 12.5/ 15mg KwikPen
מאונג'רו 2.5/ 5/ 7.5/ 10/12.5/ 15 מ"ג קוויקפן
Solution for Injection

חברת לילי מבקשת להודיעכם כי העלון לרופא של התכשיר שבנידון עודכן.
השינויים בעלון מסומנים במכתב זה.
העלונים המעודכנים לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום :
אלי לילי ישראל בע"מ, השיזף 4, רעננה , טל': 09-9606234

בברכה,
חברת אלי לילי

החומר הפעיל:

Tirzepatide

ההתוויה המאושרת לתכשיר:

Type 2 diabetes mellitus
Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.

For study results with respect to combinations, effects on glycaemic control and the populations studied, see sections 4.4, 4.5 and 5.1.

Weight management
Mounjaro is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of

- ≥ 30 kg/m^2 (obesity) or
- ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus).

For trial results with respect to obstructive sleep apnoea (OSA) in adults with obesity, see section 5.1.

השינויים בעלון לרופא הם

5.1 Pharmacodynamic properties

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SURMOUNT-5
In a 72-week study, 751 adult patients with obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2 to < 30 kg/m^2) with at least 1 weight-related comorbid condition were randomised to tirzepatide 15 mg or semaglutide 2.4 mg once weekly. When patients did not tolerate this dose, the dose was reduced to tirzepatide 10 mg or semaglutide 1.7 mg once weekly. Patients were counselled on a

Eli Lilly Israel LTD. 4 HaSheizaf St.
P.O.Box 4246,Ra'anana 4366411
Tel: 972-9-9606234, Fax: 972-9-9576001

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reduced calorie diet and increased physical activity throughout the trial. Participants had a mean age of 44.7 years and a mean BMI of 39.4 kg/m^2. Overall, 64.7 % were female.

Treatment with tirzepatide for 72 weeks resulted in a superior and clinically meaningful reduction in body weight compared to semaglutide. The percent change from baseline at week 72 (primary endpoint) was -21.6 % for tirzepatide and -15.4 % for semaglutide (difference from semaglutide: -6.2 %; 95 % CI [-7.8, -4.6]; p<0.001). Tirzepatide also achieved superiority compared with semaglutide for the key secondary endpoints, i.e. proportion of patients achieving ≥10 %, ≥15 %, ≥20 %, and ≥25 % body weight reduction at week 72 as well as reduction of waist circumference at week 72.

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