Answers That Matter.

מרץ 2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

מאונג'רו 2.5 /5 / 7.5 / 10 / 12.5 / 15 מ"ג / 0.5 מ"ל
Mounjaro 2.5/ 5/ 7.5/ 10/ 12.5/ 15mg / 0.5ml
Solution for Injection

חברת לילי מבקשת להודיעכם כי העלונים לרופא ולצרכן והוראות השימוש של התכשיר שבנידון עודכנו.
בהודעה זו מצוינים רק הסעיפים בהם נעשה שינוי המהווה החמרה. קיימים עדכונים נוספים.
טקסט שהתווסף מודגש בצבע צהוב.
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:

T2DM
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.

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/m2 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).

העדכונים העיקריים בעלון לרופא הינם:

4.8 Undesirable effects

Tabulated list of adverse reactionsThe following related adverse reactions from clinical studies are listed below by system organ class and in order of decreasing incidence (very common: ≥ 1/10; common: ≥ 1/100 to < 1/10; uncommon: ≥ 1/1,000 to < 1/100; rare: ≥ 1/10,000 to < 1/1,000; very rare: < 1/10,000). Within each incidence grouping, adverse reactions are presented in order of decreasing frequency.

Table 1. Adverse reactions

System organ class	Very common	Common	Uncommon	Rare
…				
Nervous system disorders		Dizziness[2]	Dysgeusia, Dysaesthesia	

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Vascular disorders		Hypotension[2]		
Gastrointestinal disorders	Nausea, Diarrhoea, Vomiting[3], Abdominal pain[3], Constipation[3]	Dyspepsia, Abdominal distention, Eructation, Flatulence, Gastroesophageal reflux disease	Cholelithiasis, Cholecystitis, Acute pancreatitis, Delayed gastric emptying	
…				

Description of selected adverse reactions

Gallbladder-related events

In a pool of 3 placebo-controlled weight management phase 3 studies, the overall incidence of cholecystitis and cholecystitis acute was 0.6 % and 0.2 % for tirzepatide- and placebo-treated patients, respectively.

In a pool of 3 placebo-controlled weight management phase 3 studies, acute gallbladder disease was reported ~~by~~ in up to 2.0 % of tirzepatide-treated patients and in up to 1.6 % of placebo-treated patients.

~~These acute gallbladder events were positively associated with weight reduction.~~

In the weight management phase 3 studies, acute gallbladder events were positively associated with weight reduction.

Immunogenicity

There was no evidence of an altered pharmacokinetic profile or an impact on efficacy of tirzepatide associated with the development of anti-drug antibodies (ADA) or neutralising antibodies.

5,025 tirzepatide-treated patients in the T2DM phase 3 clinical studies were assessed for ADA. Of these, 51.1 % developed treatment-emergent (TE) ADA during the on-treatment period. In 38.3 % of the assessed patients, TE ADA were persistent (that is TE ADA present for a period of 16 weeks or greater). 1.9 % and 2.1 % had neutralising antibodies against tirzepatide activity on the glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptors, respectively and 0.9 % and 0.4 % had neutralising antibodies against native GIP and ~~GLP-1, respectively. There was no evidence of an altered pharmacokinetic profile or an impact on efficacy of tirzepatide associated with the development of ADA~~ native GLP-1, respectively.

~~3,484~~ 3,710 tirzepatide-treated patients in the 4 phase 3 weight management studies were assessed for ADA. Of these, 65.1 % developed TE ADA during the on-treatment period. In 51.3 % of the assessed patients, TE ADA were persistent. Up to 2.3 % and 2.3 % had neutralising antibodies against tirzepatide activity on the GIP and GLP-1 receptors, respectively and up to 0.7 % and 0.1 % had neutralising antibodies against native GIP and native GLP-1, respectively.

העדכונים העיקריים בעלון לצרכן הינם:

4. תופעות לוואי

תופעות לוואי שאינן שכיחות (עלולות להשפיע על עד 1 מתוך 100 אנשים)

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- שינוי בתחושת העור
- עיכוב בריקון הקיבה

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