פברואר 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת אלי לילי מבקשת להודיעכם על עדכון העלונים לרופא ולצרכן של התכשירים:

מאונג'רו 2.5 מ"ג קוויקפן	**Mounjaro 2.5 mg KwikPen**
מאונג'רו 5 מ"ג קוויקפן	**Mounjaro 5 mg KwikPen**
מאונג'רו 7.5 מ"ג קוויקפן	**Mounjaro 7.5 mg KwikPen**
מאונג'רו 10 מ"ג קוויקפן	**Mounjaro 10 mg KwikPen**
מאונג'רו 12.5 מ"ג קוויקפן	**Mounjaro 12.5 mg KwikPen**
מאונג'רו 15 מ"ג קוויקפן	**Mounjaro 15 mg KwikPen**

טקסט שהתווסף מסומן בכחול וטקסט שנמחק מסומן באדום. קיימים עדכונים נוספים שאינם מסומנים במכתב זה.

העלונים המעודכנים 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,
ליאת אטיאס
רוקחת ממונה
אלי לילי ישראל בע"מ

החומר פעיל: Tirzepatide

צורת מינון: Solution for injection

ההתוויות המאושרות 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.

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.

העדכונים המרכזיים בעלון לרופא הינם:

4.6 Fertility, pregnancy and lactation

Following a single 5 mg dose, the concentration of tirzepatide in breast milk was found to be undetectable to very low compared to plasma concentrations. As tirzepatide is an amino acid sequence, any low amount present in breast milk is expected to be degraded and not orally absorbed as intact drug by the breastfed infant.

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~~It is unknown whether tirzepatide is excreted in human milk. A risk to the newborn/infant cannot be excluded.~~

It is not known whether the reduced maternal food intake caused by tirzepatide affects composition or nutrient content of the breast milk. Overall, tirzepatide could be considered for use during breast-feeding.

~~A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from tirzepatide therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.~~

4.8 Undesirable effects

Tabulated list of adverse reactions

[…]

Table 1. Adverse reactions

System organ class	Very common	Common	Uncommon	Rare
Immune system disorders		Hypersensitivity reactions		Anaphylactic reaction[#], Angioedema[#]
Metabolism and nutrition disorders	Hypoglycaemia[1]* when used with sulphonylurea or insulin	Hypoglycaemia[1]* when used with metformin and SGLT2i, Decreased appetite[1]	Hypoglycaemia[1]* when used with metformin, Weight decreased[1]	
Nervous system disorders		Dizziness[2]	Dysgeusia, Dysaesthesia	
Vascular disorders		Hypotension[2]		
Gastrointestinal disorders	Nausea, Diarrhoea, Vomiting[3], Abdominal pain[3], Constipation[3,4]	Dyspepsia, Abdominal distention, Eructation, Flatulence, Gastroesophageal reflux disease	Cholelithiasis, Cholecystitis, Acute pancreatitis, Delayed gastric emptying	
Skin and subcutaneous tissue disorders		Hair loss[2]		
General disorders and administration site conditions		Fatigue[†], Injection site reactions	Injection site pain	
Investigations		Heart rate increased, Lipase increased, Amylase increased, Blood calcitonin increased[4,5]		

[#]From post-marketing reports

*Hypoglycaemia defined below.

[†]Fatigue includes the terms fatigue, asthenia, malaise, and lethargy.

[1] Adverse reaction that only applies to patients with type 2 diabetes mellitus (T2DM).

[2] Adverse reaction that mainly applies to patients with overweight or obesity, with or without T2DM.

[3] Frequency was very common in weight management and OSA trials, and common in T2DM trials.

[4] Frequency was very common in weight management and OSA trials, and ~~un~~common in T2DM ~~and OSA~~ trials.

[5] Frequency was common in weight management trials and uncommon in ~~adult~~ T2DM and OSA trials.

Description of selected adverse reactions

Hypersensitivity reactions

Hypersensitivity reactions have been reported with tirzepatide in ~~the~~ pooled ~~of~~ T2DM placebo-controlled trials, pooled placebo-controlled weight management trials and pooled placebo-controlled OSA trials, sometimes severe (e.g., urticaria, ~~and~~ eczema, rash, dermatitis~~;~~). H~~h~~ypersensitivity reactions were reported in 3.2 %, 5.0% and 3.0% of tirzepatide-treated patients, respectively, compared to 1.7 %, 3.8%~~,~~ and 2.1% of placebo-treated patients, respectively.

Cases of anaphylactic reaction and angioedema have been rarely reported with marketed use of tirzepatide.

~~Hypersensitivity reactions have been reported with tirzepatide in a pool of 3 placebo-controlled weight management trials and in a pool of 2 placebo-controlled OSA trials, sometimes severe (e.g., rash and dermatitis); hypersensitivity reactions were reported in 3.0 - 5.0 % of tirzepatide-treated patients compared to 2.1 - 3.8 % of placebo-treated patients.~~

[...]

Gallbladder-related events

In ~~a pool of 3~~pooled 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~~pooled placebo-controlled weight management phase 3 studies and in ~~a pool of 2~~pooled placebo-controlled OSA phase 3 studies, acute gallbladder disease was reported in ~~up to~~ 2.0 % and 0.9% of tirzepatide-treated patients, respectively, and in ~~up to~~ 1.6 % and 0.9 % of placebo-treated patients, respectively.

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

Immunogenicity

In phase 3 clinical studies, a total of 8735 ~~5,025~~ tirzepatide-treated patients ~~in the T2DM phase 3 clinical studies~~ were assessed for anti-drug antibodies (ADA). Across ~~ADA. Of~~ these studies, 51.1~~—~~-65.1 % developed treatment-emergent (TE) ADA during the on-treatment period. In 38.3~~-—~~51.3 % of the assessed patients, TE ADA were persistent (that is TE ADA present for a period of 16 weeks or greater). ~~1.9~~Up to 2.3 % and 2.~~1~~ 3 % had neutralising antibodies against tirzepatide activity on the glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptors, respectively and up to 0.9 % and 0.4 % had neutralising antibodies against native GIP and native GLP-1, respectively.

~~3,710 tirzepatide-treated patients in the 4 phase 3 weight management and 2 phase 3 OSA studies were assessed for ADA. Of these, 60.6 - 65.1 % developed TE ADA during the on-treatment period. In 46.5 - 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.~~

Heart rate

In ~~the~~ pooled placebo-controlled T2DM phase 3 studies, treatment with tirzepatide resulted in a maximum mean increase in heart rate of 3 to 5 beats per minute ~~.~~ across doses. The maximum mean increase in heart rate in placebo-treated patients was 1 beat per minute.

The percentage of patients who had a change of baseline heart rate of > 20 bpm for 2 or more consecutive visits was 2.1 %, 3.8 % and 2.9 %, for tirzepatide 5 mg, 10 mg and 15 mg, respectively, compared with 2.1 % for placebo.

Small mean increases in PR interval were observed with tirzepatide when compared to placebo (mean increase of 1.4 to 3.2 msec and mean decrease of 1.4 msec respectively). No difference in arrhythmia and cardiac conduction disorder treatment emergent events were observed between tirzepatide 5 mg, 10 mg, 15 mg and placebo (3.8 %, 2.1 %, 3.7 % and 3 % respectively).

In ~~3~~ pooled placebo-controlled weight management phase 3 studies and in pooled placebo-controlled OSA phase 3 studies, treatment with tirzepatide resulted in a mean increase in heart rate of 3 and 2 beats per minute, respectively. There was ~~no~~ a mean increase in heart rate of <1 and <1 beat per minute, respectively, in ~~the placebo~~ placebo-treated patients.

[...]

Injection site reactions

In ~~the~~ pooled placebo-controlled T2DM phase 3 studies, ~~injection site reactions were increased for tirzepatide (3.2 %) compared with placebo (0.4 %). In~~ in ~~3~~ pooled placebo-controlled weight management phase 3 studies and in ~~2~~ pooled placebo-controlled OSA phase 3 studies, injection site reactions were increased for tirzepatide (3.2 %, 8.0~~2~~ % and 8.~~6~~ 2 %, respectively) compared with placebo (0.4 %, 1.8 % and 2.6 %, respectively).

Overall, in phase 3 studies, the most common signs and symptoms of injection site reactions were erythema and pruritus. The maximum severity of injection site reactions for patients was mild (91 %) or moderate (9 %). No injection site reactions were serious.

Pancreatic enzymes

In ~~the~~ pooled placebo-controlled T2DM phase 3 studies, treatment with tirzepatide resulted in mean increases from baseline in pancreatic amylase of 33 % to 38 % and lipase of 31 % to 42 % across doses. Placebo treated patients had an increase from baseline in amylase of 4 % and no changes were observed in lipase.

In ~~3~~ pooled placebo-controlled weight management phase 3 studies and in pooled ~~2~~ placebo-controlled OSA phase 3 studies, treatment with tirzepatide resulted in mean increases from baseline in pancreatic amylase of 23 % and 25%, respectively, ~~24.6 %~~ and lipase of 34 % and~~-~~ 39 %, respectively. Placebo treated patients had an increase from baseline in amylase of ~~0.7~~2 % and 1~~.8~~ %, respectively and in lipase of 6% and 4 %, respectively~~3.5 - 5.7 %~~.

[…]

6.6 Special precautions for disposal and other handling

[…]

A small amount of Mounjaro solution for injection may remain in the KwikPen after all 4 doses have been correctly given. Patients should be instructed not to try to use the remaining Mounjaro solution for injection, but to properly discard the KwikPen.

העדכונים העיקריים בעלון לצרכן הינם:

2. <u>לפני השימוש בתרופה</u>

[...]

הנקה

<u>טירזפאטייד עוברת לחלב אם בכמויות נמוכות מאוד ואינה צפויה להיספג על ידי יילוד/תינוק יונק</u>. ~~לא ידוע האם טירזפאטייד עוברת לחלב האם. לא ניתן לשלול סיכון לילודים/תינוקות. אם את מיניקה או מתכננת להניק,~~ אם את מיניקה או מתכננת להניק, ~~דברי~~ <u>שוחחי</u> עם הרופא לפני השימוש <u>או לגבי המשך השימוש</u> בתרופה זו. ~~את והרופא צריכים להחליט האם עליך להפסיק להניק או לדחות את השימוש במאונג'רו.~~

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