

הנדון: עדכון עלוני התכשיר Ozempic

מספר רישום: 162-09-35750

חברת נובו נורדיסק בע"מ מבקשת ליידע על עדכוני בטיחות בעלוני התכשיר Ozempic כמפורט להלן.

חומר פעיל: Semaglutide

ההתוויה הרשומה לתכשיר:

Ozempic 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.

בוצעו עדכונים בעלון לרופא ובעלון לצרכן. בהודעה זו מצוינים העדכונים המהותיים בלבד. טקסט **שהתווסף** לעלון מסומן מטה בכחול, החמרות מסומנות ברקע **צהוב**. טקסט **שנמחק** מהעלון מסומן בקו-חוצה. נא לעיין בעלוני המצורפים להודעה זו המכילים את כלל העדכונים.

עדכונים בעלון לרופא:

4.8 Undesirable effects

[...]

Table 1 Frequency of adverse reactions of semaglutide

MedDRA system organ class	Very common	Common	Uncommon	Rare	Not Known
Nervous system disorders		Dizziness Headache	Dysgeusia		

[...]

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

[...]

A phase 3b functional capacity trial (STRIDE), including 792 patients, was conducted to investigate the effects of semaglutide 1 mg once weekly vs placebo in patients with type 2 diabetes and peripheral arterial disease.

[...]

In a 52-week double blind trial (STRIDE, NCT04560998), 792 patients with T2D and PAD with intermittent claudication Fontaine stage IIa were randomised to either semaglutide 1 mg once weekly or placebo on top of standard of care. The primary endpoint was change in maximum walking distance on a constant load treadmill test from baseline to week 52. The confirmatory secondary endpoints were change in Vascular Quality of Life Questionnaire-6 (VascuQoL-6) score from baseline to week 52 and change in pain-free walking distance from baseline to week 52. VascuQoL-6 is a questionnaire which includes the domains pain, social and emotional impact, and activity limitations. The score ranges from 6 to 24, with higher scores indicating better health status. The mean age of the study population was 67 years, and 75.4% of patients were male. Mean BMI was 29.6 kg/m² and mean diabetes duration was 13.3 years.

In STRIDE, treatment with semaglutide 1 mg once-weekly resulted in a statistically significant improvement in the functional capacity outcomes (maximum walking distance, pain-free walking distance) and patient reported symptoms and impacts of intermittent claudication (VascuQoL-6 total score) at week 52 compared to placebo. The 13% relative improvement represents a median change in maximum walking distance of 26 meters on constant load treadmill [12 – 41] 95% CI (Table 8).

Table 8: Functional capacity outcomes and VasuQoL-6 total score from STRIDE

Intention-to-treat ^a	Ozempic N = 396	Placebo N = 396
Maximum walking distance (meters)		
Week 52		
Baseline ^b median	184.50	185.75
Ratio to baseline median	1.21	1.08
Treatment ratio (HL Estimate) [95% CI] ^c	1.13 [1.056, 1.211]*	
Patients (%) experiencing meaningful within-patient change ^d	49.1	35.1
Pain-free walking distance (meters), week 52		
Baseline ^b median	119.00	109.00
Ratio to baseline median	1.21	1.10
Treatment ratio (HL Estimate) [95% CI] ^c	1.11 [1.033, 1.197]*	
VasculQoL-6 total score, week 52		
Baseline median	15.0	15.0
Change from baseline median	2.0	1.0
Treatment difference (HL Estimate) [95% CI] ^c	1.00 [0.478, 1.518]*	

HL = Hodges-Lehmann estimate of location shift (median of all paired differences between semaglutide and placebo); CI = confidence interval; PAD = Peripheral arterial disease.
^a The intention-to-treat population includes all randomized patients. Missing data at week 52 due to death or physical inability to perform treadmill assessments were handled using composite strategy. Missing data at post-baseline visits for other reasons were imputed using multiple imputation within groups defined by randomised treatment and completion status at week 52.

^b Baseline was defined as the average of the walking distance measurements taken at baseline visit (week 0).

^c 95% CIs were estimated with the Hodges-Lehmann method.

* p < 0.05 (two-sided) for superiority of semaglutide vs. placebo obtained from Wilcoxon-rank sum test, adjusted for multiplicity.

^d The meaningful within-patient change for maximum walking distance at week 52 is defined as an improvement of at least 1.2 (20%) relative to baseline walking distance. These estimates were obtained from the anchor-based analysis based on 1-category improvement in the PGI-S (Patient Global Impression of Severity) scale. The binary endpoint was analysed using a logistic regression model with randomised treatment as a fixed factor.

עדכונים בעלון לצרכן:

4. תופעות לוואי

[...]

תופעות לוואי שכיחות: עשויות להשפיע על עד משתמש אחד מתוך 10 משתמשים

[...]

כאב ראש

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום: נובו נורדיסק בע"מ, רח' עתיר ידע 1, כפר-סבא 4464301, ישראל. טלפון: 09-7630444.

בברכה,

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רוקחת ממונה

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