רופא/ה, רוקח/ת נכבד/ה,

פברואר 2025

Wegovy 0.25mg, 0.5mg, 1mg, 1.7mg and 2.4mg
Solution for injection

חברת נובו נורדיסק בע"מ מבקשת ליידע על עדכון העלונים של התכשיר וויגובי.

<u>חומר פעיל:</u>

<u>Wegovy 0.25 mg</u> - semaglutide 0.68 mg/ml
<u>Wegovy 0.5 mg</u> - semaglutide 1.34 mg/ml
<u>Wegovy 1 mg</u> - semaglutide 1.34 mg/ml
<u>Wegovy 1.7 mg</u> - semaglutide 2.27 mg/ml
<u>Wegovy 2.4 mg</u> - semaglutide 3.2 mg/ml

<u>ההתוויה הרשומה לתכשיר:</u>

Adults
Wegovy 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 comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.

Adolescents (≥12 years)
Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with

- obesity* and
- body weight above 60 kg.

Treatment with Wegovy should be discontinued and re-evaluated if adolescent patients have not reduced their BMI by at least 5% after 12 weeks on the 2.4 mg or maximum tolerated dose.

*Obesity (BMI ≥95th percentile) as defined on sex- and age-specific BMI growth charts (CDC.gov) (see Table 1).

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Table 1 BMI cut-off points for obesity (≥95th percentile) by sex and age for paediatric patients aged 12 and older (CDC criteria)

Age (years)	BMI (kg/m^2) at 95th Percentile	
	Males	Females
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

בהודעה זו מצוינים העדכונים המהותיים בלבד. טקסט באדום עם קו תחתי מציין טקסט שהוסף לעלון. החמרות מסומנות ברקע צהוב. נא לעיין בעלונים המצורפים להודעה זו המכילים את כלל העדכונים.

עדכונים בעלון לרופא:

4.8 Undesirable effects

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Table 3 Frequency of adverse reactions of semaglutide

MedDRA system organ class	Common
Nervous system disorders	Dizziness[b] Dysgeusia[b,c] Dysaesthesia[a]

Description of selected adverse reactions

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Dysaesthesia

Events related to a clinical picture of altered skin sensation such as paraesthesia, pain of skin, sensitive skin, dysaesthesia and burning skin sensation were reported in 2.1% of patients treated with semaglutide 2.4 mg and 1.2% of patients treated with placebo. The events were mild to moderate in severity and most patients recovered while on continued treatment

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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STEP 9: Weight management in patients with knee osteoarthritis

In a 68-week double-blind trial, 407 patients with obesity and moderate knee osteoarthritis (OA) of one or both knees were randomised to either semaglutide or placebo, as an adjunct to counselling on a reduced-calorie diet and increased physical activity. The treatment effect on knee OA-related pain was assessed by the Western Ontario and McMaster Universities Osteoarthritis 3.1 Index (WOMAC). This index is designed to evaluate changes in symptoms and lower extremity functioning associated with treatment in patients suffering from OA of the hip and/or knee. At baseline, patients had a mean BMI of 40.3 kg/m^2 and a mean body weight of 108.6 kg. All patients had a clinical diagnosis of knee OA with a mean baseline WOMAC pain score of 70.9 (on a scale of 0-100).

Treatment with semaglutide for 68 weeks resulted in superior and clinically significant reduction in body weight compared to placebo (see Table 10).

Treatment with semaglutide demonstrated a clinically meaningful improvement in knee OA-related pain compared to the placebo (see Table 10). The improvements in knee OA-related pain with semaglutide were achieved without an increase in the use of pain medication.

Table 10 STEP 9: Results at week 68

	Semaglutide 2.4 mg	**Placebo**
Full analysis set (N)	271	136
Body weight		
Baseline (kg)	108.7	108.5
Change (%) from baseline[1,2]	-13.7	-3.2
Difference (%) from placebo[1] [95% CI]	-10.5 [-12.3; -8.6]*	-
Patients (%) achieving weight loss ≥5%[3]	85.2*	33.6
WOMAC pain score[4]		
Baseline	72.8	67.2
Change from baseline[1,2]	-41.7	-27.5
Difference from placebo[1] [95% CI]	-14.1 [-20.0, -8.3]*	-
Patients (%) achieving clinically meaningful improvement [3, 5]	59.0	35.0

* p< 0.0001 (unadjusted 2-sided) for superiority.

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[1] Estimated using an ANCOVA model using multiple imputation based on all data irrespective of discontinuation of randomised treatment or initiation of other anti-obesity therapies or other knee OA interventions and regardless of compliance with wash out period for pain medication (the latter only relevant for WOMAC related endpoint). During the trial, randomised treatment was permanently discontinued by 12.5% and 21.3% of patients randomised to semaglutide 2.4 mg and placebo, respectively.

[2] Based on a Mixed Model for Repeated Measures assuming that all randomised patients stayed on treatment and did not receive additional anti-obesity therapies or additional knee OA interventions and complied with washout period for pain medication (the latter only relevant for knee OA related pain), including all observations until first discontinuation the estimated changes from baseline to week 68 for body weight were -14.5% and -2.3% (semaglutide 2.4 mg and placebo, respectively) and for WOMAC pain score: -43.0 and -28.3 (semaglutide 2.4 mg and placebo, respectively).

[3] Estimated from logistic regression model based on same imputation procedure as for the primary analysis.

[4] WOMAC scores are presented on a scale from 0-100, with lower scores representing less disability.

[5] The change in WOMAC pain score of ≤ -37.3 was used as a threshold for meaningful improvement. The threshold was derived from trial data using anchor-based methods.

עדכונים בעלון לצרכן:

4. תופעות לוואי

כמו בכל תרופה, השימוש בוויגובי עלול לגרום לתופעות לוואי בחלק מהמשתמשים. אל תיבהל למקרא רשימת תופעות הלוואי. ייתכן שלא תסבול מאף אחת מהן.

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תופעות לוואי שכיחות (עלולות להופיע בעד משתמש אחד מתוך 10)

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- שינוי בתחושת העור

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העלונים המעודכנים מפורסמים 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.
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