Oral semaglutide 50 mg for obesity

Potential treatment under drug development

With more than 800 million people living with obesity,[1] an individualised treatment approach is needed with differentiated offerings to help people with obesity receive quality care.

Oral semaglutide 50 mg is not yet approved for use in weight loss; regulatory filings are planned for 2023.

OASIS 1: A phase 3a trial in the global OASIS programme

A 68-week study investigating the efficacy and safety of once-daily oral semaglutide 50 mg versus placebo for weight management in adults with obesity or overweight with one or more comorbidities.[2]

Approximately **667 adults** living with obesity *(BMI ≥30 kg/m²)* or overweight *(BMI ≥27 kg/m²)* with at least one weight-related comorbidity, and without history of diabetes or HbA_{1c} ≥6.5%.[3]

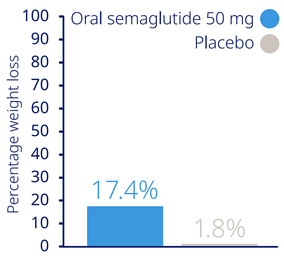
Participants received **oral semaglutide 50 mg or placebo** as an adjunct to lifestyle intervention *(counselling, a reduced-calorie diet and increased physical activity)*.[3]

Primary endpoints of **change in body weight over 68 weeks** and number of participants who achieve ≥5% weight loss.[3]

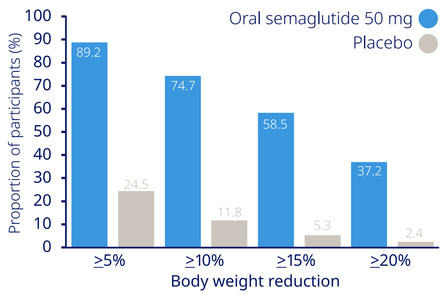
Key data from OASIS 1

Results showed statistically significant and superior body weight reductions at Week 68 for oral semaglutide 50 mg compared to placebo, according to the two statistical approaches used in the study[a]:

The treatment effect assuming that all participants in the trial complied to the randomised treatment without initiating any other anti-obesity therapies*

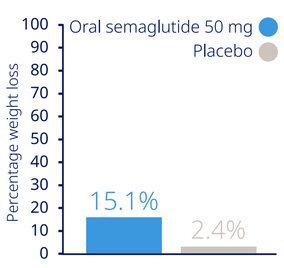


People treated with oral semaglutide 50 mg achieved a weight loss of **17.4%** compared to a **1.8%** reduction with placebo[3]

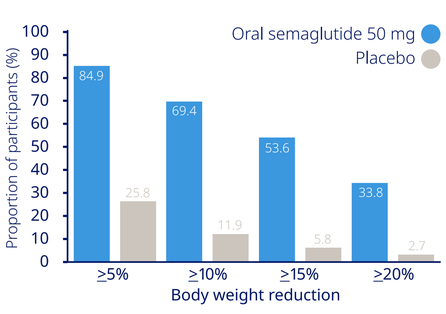


Around 6 out of 10 people treated with oral semaglutide 50 mg lost **≥15%** of body weight, and **4 out of 10 lost ≥20%**[4]

The treatment effect in all participants who had undergone randomisation, regardless of adherence to their assigned treatment or use of other anti-obesity therapies†



People treated with oral semaglutide 50 mg achieved a weight loss of **15.1%** compared to a **2.4%** reduction with placebo[3]



Around 5 out of 10 people treated with oral semaglutide 50 mg lost **≥15%** of body weight, and **3 out of 10 lost >20%**[4]

Oral semaglutide 50 mg had a safe and well-tolerated profile similar to that observed in previous trials with GLP-1 RAs.[5] The most common adverse events were gastrointestinal, of which the majority were mild to moderate and diminished over time.[3]

[a] Participants had a mean baseline body weight of 105.4 kg.

*Also known as trial product estimand.

† Also known as treatment policy estimand.

References:

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3. Novo Nordisk A/S. Oral semaglutide 50 mg achieved 15.1% weight loss (17.4% if all people adhered to treatment) in adults with obesity or overweight in the OASIS 1 trial. Available at: https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166110. Last accessed: May 2023.
4. Knop FK. Symposium: Oral Semaglutide for Treatment of Obesity and Type 2 Diabetes – Results from OASIS 1 and PIONEER PLUS Trials. ADA 2023. June 25, 2023.
5. Shetty R, Basheer FT, Poojari PG, *et al*. Adverse drug reactions of GLP-1 agonists: A systematic review of case reports. *Diabetes Metab Syndr* 2022; 16:102427.

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