Think you know the truth about compounded “semaglutide”?

Important facts to know if you or someone you care for is considering an unapproved compounded product:


Actor portrayals

FACT ONE

Compounded “semaglutide” is not an FDA-approved medicine.

- It can be risky for patients to use unapproved versions of compounded “semaglutide” because they **do not undergo FDA’s review for safety, effectiveness, and quality**.[1]
- May be made by pharmacies that are **not requried to do surveillance, evaluation or reporting of adverse events** to the FDA.[1]
- Are created using ingredients not manufactured by Novo Nordisk or our authorized suppliers.

Why it matters
Unapproved compounded “semaglutide” is **not required to meet the FDA’s standards for quality, safety, and effectiveness**.[1]

At the end of the day, there’s no way of knowing exactly what is inside non-FDA-approved compounded “semaglutide”.

FACT TWO

Compounded “semaglutide” carries potential safety risks.

- Testing results have revealed that some compounded “semaglutide” samples have considerably lower strengths than indicated, making them potentially **less effective**. In one case, a product labeled as containing 1 mg/mL of semaglutide had **no semaglutide at all**.[2]
- Based on peer-reviewed scientific research, there is evidence of **high levels of known impurities and the presence of unknown impurities** in injectable compounded products claiming to contain semaglutide. In some cases, the level of unknown impurities was up to 33%.[2, 3]
- Impurities in compounded drugs have the potential to **trigger an immune reaction** upon repeated injections, which may lead to serious and life-threatening responses.[2, 3]

FACT THREE

Don’t take our word for it. The FDA is warning consumers.

- Unlike sponsors of FDA-approved medicines, c**ompounding pharmacies are not required to do surveillance, evaluation, or reporting of adverse events to the FDA**. The FDA has warned that “it is likely that adverse events from compounded versions of these drugs are **underreported**.”[1]
- In several instances, patients using a multi-dose vial and syringe have mistakenly administered **five to 20 times more** than the intended dose of compounded “semaglutide.”[4]
- The safety and effectiveness of compounding semaglutide with **additional ingredients** found in compounded versions of “semaglutide” has not been established.[4]

Visit **semaglutide.com** to learn more about medicines containing semaglutide and their safe use.

References

[1] FDA’s concerns with unapproved GLP-1 drugs used for weight loss. U.S. Food and Drug Administration. Published 2024. Accessed December 17, 2024. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[2] Data on file. Novo Nordisk Inc.; Plainsboro, NJ.

[3] Hach M, Engelund DK, Mysling S, et al. Impact of manufacturing process and compounding on properties and quality of follow-on GLP-1 polypeptide drugs. *Pharm Res*. 2024;41(10):1991-2014. doi:10.1007/s11095-024-03771-6.

[4] FDA alerts health care providers, compounders of dosing errors. U.S. Food and Drug Administration. Published 2024. Accessed December 17, 2024. https:// www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.