

Think you know the truth about compounded “semaglutide”?

Knockoff compounded “semaglutide” can be risky. Essentially all “semaglutide” used in compounding is manufactured by foreign suppliers and can use illicit active ingredients.^{1,2}

Why can unapproved knockoffs be a threat to your health? Keep reading for more information.



Actor portrayals

Compounded “semaglutide” can contain dangerous impurities, unnecessary additives, and untested doses.³⁻⁵



Dangerous Impurities and Banned Substances



Unnecessary Ingredients



Untested Doses

It can be risky.

Impurities as high as **33%**^{6,a}

Accidental overdoses **5-20x** the intended dose⁵

Some samples with **0%** semaglutide^{6,a}

^aIn some samples

Versions that melt under your tongue or against your cheek?

Don't count on them. The likelihood that they will be effectively absorbed by your body is low.^{7,8}



Compounded “semaglutide” is NOT approved by the FDA.



It's not reviewed.

Despite misleading advertising, the FDA does not review it for safety, effectiveness, or quality.¹

Safe? Not necessarily.

Without FDA approval, these products are now only made by compounding pharmacies that are not required to track, evaluate, or report side effects and adverse events.¹

Not proven.

No FDA approval means the benefits and risks are unknown.⁹

It's now illegal, with rare exceptions.⁷

Now that the shortage of injectable semaglutide is over, it's illegal to make or sell compounded “semaglutide”, with rare exceptions (an allergy to a dye, for example).¹⁰



Don't take our word for it. Experts are warning consumers.

The U.S. Food and Drug Administration, World Health Organization, and numerous other organizations and government officials are warning patients and healthcare providers about the risks of knockoff compounded “semaglutide”.^{11,11,12}

“Noncompliant healthcare providers are selling fraudulently compounded drugs claiming to contain semaglutide..., in combination with other ingredients.”¹³

—Federal Bureau of Investigation (FBI)

“...there can be errors in compounding or contamination of the product because compounding pharmacies are not held to the same standards of larger drug manufacturers.”¹⁴

—National Capital Poison Center

FDA-approved treatments exist and are fully available. Visit semaglutide.com to learn more about them.

References

¹ U.S. Food and Drug Administration (FDA). FDA's concerns with unapproved GLP-1 drugs used for weight loss. Accessed May 2025. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>. May 16, 2025.

² Partnership for Safe Medicines. New report reveals illegal ingredients for knockoff weight loss drugs flooding into U.S. from foreign sources, endangering patient safety. Accessed May 2025. <https://www.safemedicines.org/2025/02/new-report-reveals-illegal-ingredients-for-knockoff-weight-loss-drugs-flooding-into-u-s-from-foreign-sources-endangering-patient-safety.html>. February 20, 2025.

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

⁴ U.S. Food and Drug Administration (FDA). Safety risks associated with certain bulk drug substances nominated for use in compounding. Accessed May 2025. <https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks>. September 27, 2024.

⁵ U.S. Food and Drug Administration (FDA). FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products. Accessed May 2025. <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>. July 26, 2024.

⁶ Novo Nordisk. Novo Nordisk escalates legal actions to safeguard patients from potentially harmful compounded “semaglutide” drugs. Accessed May 2025. <https://www.novonordisk-us.com/media/news-archive/news-details.html?id=168519>. May 30, 2024.

⁷ Wu J, Zhu C, Fan W, et al. Systemic delivery of proteins using novel peptides via the sublingual route. *J Control Release*. 2024;368:290-301.

⁸ Lam JKW, Xu Y, Worsley A, Wong ICK. Oral transmucosal drug delivery for pediatric use. *Adv Drug Deliv Rev*. 2014;73:50-62.

⁹ U.S. Food and Drug Administration (FDA). Draft guidance for industry: current good manufacturing practice—guidance for human drug compounding outsourcing facilities under section 503B of the FD&C Act. Accessed May 2025. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-guidance-human-drug-compounding-outsourcing-facilities-under>. January 7, 2021.

¹⁰ U.S. Food and Drug Administration (FDA). Compounding and the FDA: questions and answers. Accessed May 2025. <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>. November 17, 2024.

¹¹ World Health Organization. Medical product alert N°2/2024: falsified Ozempic (semaglutide). June 19, 2024. [https://www.who.int/news/item/19-06-2024-medical-product-alert-n-2-2024--falsified-ozempic-\(semaglutide\)](https://www.who.int/news/item/19-06-2024-medical-product-alert-n-2-2024--falsified-ozempic-(semaglutide)). Accessed March 31, 2025.

¹² National Association of Attorneys General. State and territory attorneys general urge FDA to take action against counterfeit and illegally sold GLP-1 drugs. Feb. 19, 2025. <https://www.naag.org/press-releases/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/>. Accessed March 31, 2025.

¹³ Federal Bureau of Investigation (FBI). Safety concerns related to fraudulent compounding practices associated with weight loss drug. Accessed May 2025. <https://www.ic3.gov/PSA/2025/PSA250228>. February 28, 2025.

¹⁴ National Capital Poison Center. What is Ozempic? Accessed May 2025. <https://www.poisson.org/articles/can-ozempic-help-me-lose-weight>.

