At Novo Nordisk, patient safety is our top priority.

All doses of FDA-approved Novo Nordisk semaglutide products are now available. As of February 21, 2025, the FDA has updated the status of all Novo Nordisk semaglutide products to "Resolved" on their drug shortage website

Potential Safety Risks of Compounded "Semaglutide"

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%.[1,2]

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.**[1]

Impurities in compounded drugs have the potential to **trigger an immune reaction** upon repeated injections, which may lead to serious and life-threatening responses.[1,2]

The FDA has highlighted:

That the safety and effectiveness of compounding semaglutide with **additional ingredients** found in compounded versions of "semaglutide" has not been established.[3]

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".[3]

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**.[4]

Based on data obtained from the FDA's Adverse Event Reporting System (FAERS) database on compounded "semaglutide" as of March 31, 2025

Adverse Event Reports:

75% were classified **as serious.[1*]**

This includes:

176 reported **hospitalizations[1]**

14 involved **deaths[1]**

Unlike sponsors of FDA-approved medicines, **compounding 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**."[4]

We are committed to raising awareness of the dangers of compounded "semaglutide" in line with our dedication to patient safety.

Based on Novo Nordisk's analysis of data from the FDA's Adverse Event Reporting System (FAERS) database as of March 31 2025, the FAERS database included 767 cases of adverse events associated with "compounded semaglutide". Of those cases, 574 (75%) were classified as serious adverse events, 176 (23%) reported hospitalization, and 14 involved deaths.

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Novo Nordisk is the **ONLY** company with FDA-approved, prescription-only medicines containing semaglutide

No FDA-approved generic semaglutide currently exists

The FDA requires **rigorous scientific examination** of pharmaceuticals to ensure safety and efficacy. This includes oversight of the production of *active pharmaceutical ingredients (API)* and regulations on manufacturing which may include FDA inspections and audits[5, 6]

The API used in Novo Nordisk's FDA-approved semaglutide medicines is **manufactured exclusively by Novo Nordisk and is not obtained from a third-party supplier**

Novo Nordisk **DOES NOT** provide or sell semaglutide to ANY entity for purposes of compounding "semaglutide" products

Novo Nordisk produces FDA-approved semaglutide products at sites which comply with **Current Good Manufacturing Practice (CGMP) regulations**

We care

To **combat the misinformation** that unfortunately exists online and in the public eye, we have created **semaglutide.com** to serve as a credible resource hub for U.S. audiences, including patients, healthcare professionals, and retailers.

Scan code to learn more, or visit **semaglutide.com**

For more information about the risks associated with compounded "semaglutide":

The FDA has alerted healthcare providers, compounders, and patients of the safety risks associated with compounded injectable "semaglutide" products. **To learn more about the FDA's position on compounded semaglutide, scan the QR code.**

Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives. **To read the statement, scan the QR code.**

References: 1. Data on file. Novo Nordisk Inc.; Plainsboro, NJ. **2.** Hach M, Dorthe Kot Engelund, Mysling S, et al. Impact of manufacturing process and compounding on properties and quality of follow-on glp-1 polypeptide drugs. *Pharmaceutical Research*. Published online October 8, 2024. 10.1007/s11095-024-03771-6 **3.** FDA alerts health care providers, compounders of dosing errors. U.S. Food and Drug Administration. Published 2024. https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded **4.** FDA's concerns with unapproved GLP-1 drugs used for weight loss. U.S. Food and Drug Administration. Published 2024. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss. **5.** Current good manufacturing practice (CGMP) regulations. Food and Drug Administration. Updated December 29, 2023. Accessed September 9, 2024. https://www.fda.gov/drugs/pharmaceutical-qualityresources/ current-good-manufacturing-practice-cgmp-regulations. **6.** Bays HE, Fitch A, Brown CF, et al. Frequently asked questions to the 2023 obesity medicine association position statement on compounded peptides: A call for action. *Obesity Pillars*, vol.11, Sept 2024. https://doi.org/10.1016/j.obpill.2024.100122

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