

Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss

What is semaglutide?

Semaglutide belongs to a class of medications known as glucagon-like peptide-1 (GLP-1) receptor agonists. It mimics the GLP-1 hormone that is released in the gastrointestinal tract in response to eating. One role of GLP-1 is to prompt the body to produce more insulin, which reduces blood glucose (sugar). GLP-1 in higher amounts also interacts with the parts of the brain that reduce appetite and signal a feeling of fullness.

There are currently three FDA-approved semaglutide products:

- Ozempic injection
(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf) and Rybelsus tablets
(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf) are approved to lower blood sugar levels in adults with type 2 diabetes mellitus, in addition to diet and exercise. Ozempic is also approved to reduce the risk of heart attack, stroke, or death in adults with type 2 diabetes mellitus and known heart disease.
- Wegovy injection
(https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215256s005lbl.pdf) is approved to help adults and children aged 12 years and older with obesity or some adults with excess weight (overweight), who also have weight-related medical problems, to lose weight and keep the weight off, in addition to diet and exercise.

All three medications are only available with a prescription, and there are no approved generic versions.

What is compounding?

Drug compounding (</drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>) is the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs.

Can semaglutide be compounded?

When a drug is in shortage, compounders may be able to prepare a compounded version of that drug if they meet certain requirements in the Federal Food, Drug, and Cosmetic (FD&C) Act. As of May 2023, Ozempic and Wegovy are both listed on FDA's [Drug Shortages list](#) ([/drugs/drug-safety-and-availability/drug-shortages](#)).

Are there concerns with compounded semaglutide?

FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality.

Additionally, FDA has received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than is used the approved drugs, which contain the base form of semaglutide. The agency is not aware of any basis for compounding using the salt forms that would meet the FD&C requirements for types of active ingredients that can be compounded. On April 27, 2023, [FDA wrote to the National Association of Boards of Pharmacy](#) ([/media/168390/download](#)) expressing the agency's concerns with use of the salt forms in compounded products.

What should patients know?

Patients should be aware that some products sold as 'semaglutide' may not contain the same active ingredient as FDA-approved semaglutide products and may be the salt formulations. Products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective.

Patients should only obtain drugs containing semaglutide with a prescription from a licensed health care provider, and only obtain medicines from state-licensed pharmacies or outsourcing facilities registered with FDA.

Purchasing medicine online from unregulated, unlicensed sources can expose patients to potentially unsafe products that have not undergone appropriate evaluation or approval, or do not meet quality standards. If you choose to use an online pharmacy, FDA's [BeSafeRx](#) ([/drugs/quick-tips-buying-medicines-over-internet/besafex-your-source-online-pharmacy-information](#)) campaign resources and tools can assist in making safer, more informed decisions when purchasing prescription medicine online.

What should health care professionals know?

Health care professionals who are considering working with compounders to obtain semaglutide products should be aware that compounders may be using salt forms of semaglutide. FDA is not aware of any basis for compounding a drug using semaglutide salts that would meet federal requirements.

Reporting issues to the FDA

FDA encourages health care professionals, patients, and compounders to report adverse events or quality problems with these or any medications to FDA's [MedWatch Adverse Event Reporting](#) ([/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program](#)) program:

- Complete and submit the report [online](#) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>); or
- Download and complete the [form](#) (<https://www.fda.gov/media/85598/download>), then submit it via fax at 1-800-FDA-0178.

More Resources

- [Drug Compounding and Drug Shortages](#) ([/drugs/human-drug-compounding/drug-compounding-and-drug-shortages](#)).
- [Compounding and the FDA: Questions and Answers](#) ([/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers](#)).