FDA warns of accidental overdoses from compounded versions of Ozempic

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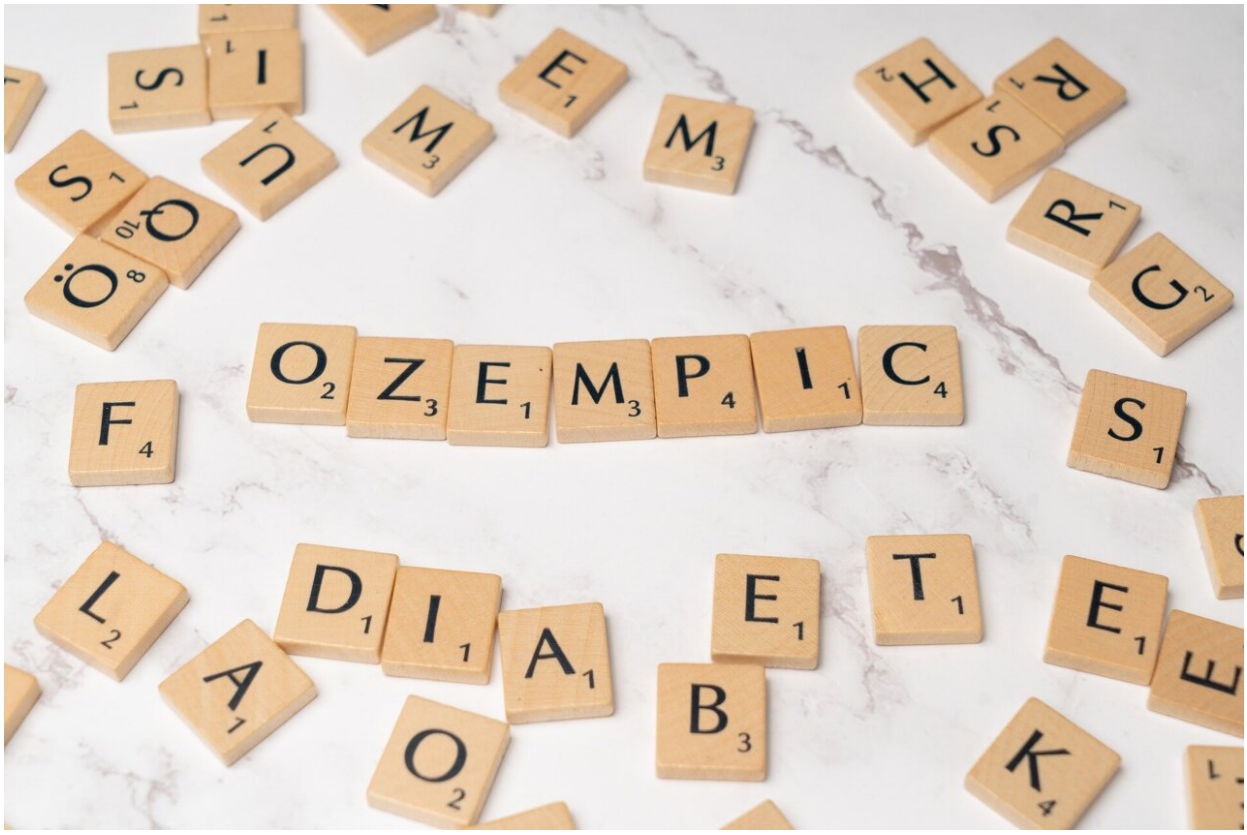

Credit: Pixabay/CC0 Public Domain

People taking compounded versions of Ozempic have been overdosing on the drug, the U.S. Food and Drug Administration warns.

These ODs typically are due to miscommunications or miscalculations regarding dosage, the FDA added.

"Dosing errors have resulted from patients measuring and self-administering incorrect doses of the drug and health care providers miscalculating doses of the drug," the FDA alert said.

Health problems caused by overdoses of compounded semaglutide—the main ingredient in Ozempic and Wegovy—include severe nausea, vomiting and hypoglycemia, the FDA said. Other side effects include fainting, headache, migraine, dehydration, pancreatitis and gallstones.

People who have a severe overdose might need to be kept for observation for an extended period, since the half-life of semaglutide is about a week, the FDA said.

Drug compounding involves combining, mixing or altering drugs to create a medication tailored to the needs of an individual patient.

"FDA is aware of compounded semaglutide products that are being marketed for weight loss," the agency said. "Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness."

"Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug," the agency added.

Compounded semaglutide products can come in varying concentrations, and often are provided in multiple-use vials with potentially confusing dose instructions, the FDA said.

"The majority of the reports described patients mistakenly drawing up more than the prescribed dose from a multiple-dose vial during self-administration," the FDA said.

"In these instances, patients administered five to 20 times more than the intended dose of semaglutide," the agency added. "Most of the reports indicated that patients were unfamiliar with how to measure the intended dose using a syringe."

In several reports, patients were given a 1-milliliter (ml) insulin syringe to draw small doses from a multiple-dose vial.

The patients were told to draw a 5-unit dose, meant to be 0.05 ml. Using the syringe's markings, they mistakenly drew a 50-unit dose of 0.5 ml, the FDA said.

In one case, a patient went online searching for medical advice after not receiving clear dosing instructions from the telemedicine provider who prescribed their compounded semaglutide, the FDA said. They wound up taking five times the intended dose.

In contrast, FDA-approved injectable semaglutide products are safer: They're only available in pre-filled pens, have standard concentrations and are dosed in milligrams.

In several reports, health care providers have incorrectly calculated the intended dose of compounded semaglutide when converting from milligrams to either units or milliliters, the FDA said. This resulted in patients taking five to 10 times the proper dose.

For example, one patient experienced severe vomiting when a provider intended to dose 0.25 milligrams, or 5 units, instead of prescribed 25 units. That caused the patient to take five times the intended dose.

Another provider prescribed 20 units instead of 2 units, causing nausea and vomiting in three patients, the FDA said.

"FDA encourages health care providers and compounders to provide patients with the appropriate syringe size for the intended dose and counsel patients on how to measure the intended dose using the syringe," the agency said.

"Additionally, health care providers should be vigilant when prescribing and administering compounded semaglutide, as there may be different concentrations available. If uncertain, health care providers should contact the compounder about calculating the correct dose of medication to prescribe or administer," the FDA added.

More information: The FDA has more on compounding drugs.

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