

FDA issues warning about compounded versions of Wegovy, Ozempic

May 31 2023, by Cara Murez



Patients taking semaglutide for type 2 diabetes or weight loss should be



careful about where they're getting the medication, the U.S. Food and Drug Administration <u>warned</u> Tuesday.

Shortages of the drug, commonly sold as Wegovy and Ozempic, has led to the making of compounded versions of the drugs, which is combining or mixing ingredients to meet patient needs.

Compounders can make a version of a drug if the medication is in shortage and they meet requirements of the Federal Food, Drug and Cosmetic (FD&C) Act.

But the FDA said it has received reports that some <u>patients</u> have had some problems after taking the compounded drugs.

The agency warned that patients should not use a compounded drug if an approved <u>drug</u> is available.

Patients and their doctors should also understand that the FDA does not review compounded drugs for safety, effectiveness or quality. Compounded medications are not FDA-approved.

Among the issues are reports that compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than those used in the approved drugs.

The agency said it has expressed concern to the National Association of Boards of Pharmacy about the use of salt forms of semaglutide in these products.

Patients intending to use semaglutide should have a prescription from a licensed health care provider and only obtain medicines from state-licensed pharmacies or outsourcing facilities registered with FDA, the



agency said.

If buying from unregulated and unlicensed sources, patients should know they may be exposed to potentially unsafe products, the FDA cautioned.

Health care providers should also be aware that compounders may be using salt forms of semaglutide, the FDA noted.

Semaglutide mimics the GLP-1 hormone that is released by the gastrointestinal tract in response to eating. It is meant to prompt the body to produce insulin and thus lower blood glucose. It can also reduce appetite.

Three FDA-approved semaglutide products are sold in the marketplace. These include Ozempic and Rybelsus, which are approved for lowering blood sugar levels in those with type 2 diabetes. Ozempic can also be used to lower the risk of heart attack, stroke or death in adults with type 2 diabetes and heart disease.

We govy is approved to help obese and overweight people with at least one weight-related medical condition lose weight.

More information: The National Library of Medicine has more on <u>semaglutide</u>.

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Citation: FDA issues warning about compounded versions of Wegovy, Ozempic (2023, May 31) retrieved 5 May 2024 from

https://medicalxpress.com/news/2023-05-fda-issues-compounded-versions-wegovy.html

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