Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-025-CG
June 7, 2024

FDA announced that continues to investigate counterfeit Ozempic (semaglutide) injection 1 milligram (mg) in the legitimate U.S. drug supply chain and has seized thousands of units of the product. The agency advises wholesalers, retail pharmacies, health care practitioners and patients to check the product they have received and not distribute, use, or sell products labeled with lot number NAR0074 and serial number 430834149057 as pictured below. Some counterfeit products may still be available for purchase.

RECOMMENDATIONS

1. FDA recommends retail pharmacies only purchase authentic Ozempic through authorized distributors of Novo NordiskExternal Link Disclaimer and review the photographs and information to confirm the legitimacy of their shipments. Patients should only obtain Ozempic with a valid prescription through state-licensed pharmacies and check the product before using for any signs of counterfeiting.

2. Entities, including online sellers, selling counterfeit and/or tampered medicines should be reported to FDA. Suspected counterfeit products may be reported to FDA by calling your local FDA consumer complaint coordinator or by reporting it directly at report suspected criminal activity.

3. Retailers and patients may also contact Novo Nordisk customer care at 1-800-727-6500 Monday through Friday from 8:30 a.m. to 6 p.m. ET with questions or concerns.

4. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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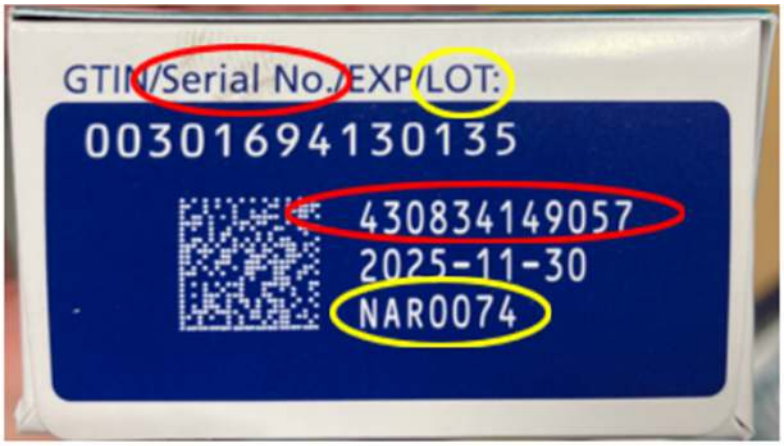
FDA U.S. FOOD & DRUG ADMINISTRATION

FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain

[12/21/2023] FDA continues to investigate counterfeit Ozempic (semaglutide) injection 1 milligram (mg) in the legitimate U.S. drug supply chain and has seized thousands of units of the product. The agency advises wholesalers, retail pharmacies, health care practitioners and patients to check the product they have received and not distribute, use, or sell products labeled with lot number NAR0074 and serial number 430834149057 as pictured below. Some counterfeit products may still be available for purchase.



FDA and Novo Nordisk (manufacturer of Ozempic) are testing the seized products and do not yet have information about the drugs' identity, quality, or safety.

Additionally, analysis found the needles from the samples are counterfeit. Accordingly, the sterility of the needles cannot be confirmed, which presents an increased risk of infection for patients who use the counterfeit products. Based on analyses completed to date, other confirmed counterfeit components within the seized products are the pen label, accompanying health care professional and patient information, and carton.

FDA is aware of five adverse events from this lot, none of which are serious and are consistent with known common adverse reactions to authentic Ozempic, which are nausea, vomiting, diarrhea, abdominal pain and constipation.

FDA recommends retail pharmacies only purchase authentic Ozempic through authorized distributors of Novo NordiskExternal Link Disclaimer and review the photographs and information

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to confirm the legitimacy of their shipments. Patients should only obtain Ozempic with a valid prescription through state-licensed pharmacies and check the product before using for any signs of counterfeiting.

FDA takes reports of possible counterfeit products seriously and works closely with other federal agencies and the private sector to help protect the nation's drug supply. FDA's investigation is ongoing, and the agency is working with Novo Nordisk to identify, investigate, and remove further suspected counterfeit semaglutide injectable products found in the U.S.

Health care professionals and consumers should report adverse events or side effects related to the use of this product to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at MedWatch Online Voluntary Reporting Form or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

Entities, including online sellers, selling counterfeit and/or tampered medicines should be reported to FDA. Suspected counterfeit products may be reported to FDA by calling your local FDA consumer complaint coordinator or by reporting it directly at report suspected criminal activity.

Retailers and patients may also contact Novo Nordisk customer care at 1-800-727-6500 Monday through Friday from 8:30 a.m. to 6 p.m. ET with questions or concerns.

Visuals of authentic and counterfeit needles are shown below:

Authentic Ozempic® Needle	Counterfeit Needle
	

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Authentic Ozempic® Needle	Counterfeit Needle
	
What to look for in a genuine needle: • The paper tab on the needle is imprinted with the needle lot number (ME61216 in this case) • The blue area on the paper tab only contains the lot number, no other text • The inner needle cover is transparent • The paper tab states 'NovoFine® Plus'	**What to look for in a counterfeit needle:** • The paper tab on the needle is imprinted with the Ozempic® product carton lot number NAR0074 • The inner needle cover has a blue transparent color • The paper tab states 'NovoFine®'

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