

# company statement

# **Update:**

**PLAINSBORO, N.J., February 20, 2024** – As an update to the December 21, 2023 company statement, which alerted consumers to counterfeit Ozempic® (semaglutide) injection 1 mg determined to be outside the Novo Nordisk authorized supply chain, Novo Nordisk is encouraging patients who have counterfeit product in their possession to return the product by calling the Novo Nordisk customer care at 1-800-727-6500 Monday through Friday from 8:30 AM to 6:00 PM EST.

Return of product only pertains to counterfeit Ozempic® (semaglutide) injection 1 mg with lot number, NAR0074, and serial number, 430834149057, as displayed below in the December company statement.

# Novo Nordisk Warns Consumers about Counterfeit Ozempic® (semaglutide) injection 1 mg in the U.S.

- Novo Nordisk has become aware of several thousand units of counterfeit Ozempic® (semaglutide) injection 1 mg determined to be outside the Novo Nordisk authorized supply chain
- Novo Nordisk cannot guarantee the quality or safety of the counterfeit Ozempic® product and is working closely with the US Food and Drug Administration
- Visual analysis show that needles and cartons appear to be counterfeit
- Product composition has not been conclusively determined at this time

**PLAINSBORO, N.J., December 21, 2023** – At Novo Nordisk, patient safety is a top priority, and we are committed to supporting the active fight against counterfeit Novo Nordisk products and other illegal activity in the market.

Novo Nordisk has become aware of several thousand units of Ozempic® (semaglutide) injection 1 mg determined to be outside the Novo Nordisk authorized supply chain. Product that contains lot number NAR0074 *and* serial number, 430834149057, as pictured below, are counterfeit and should not be used.

FDA has issued <u>an alert</u> on this counterfeit product, and Novo Nordisk is working with FDA to identify and investigate any further potential counterfeit semaglutide injectable products found in the U.S.

To date there have been five adverse events reported from this lot, all of which have been categorized as non-serious, and are consistent with the adverse event profile of authentic Ozempic\* product. It is not clear, at this time, if these incidents included legitimate product or the counterfeit product.

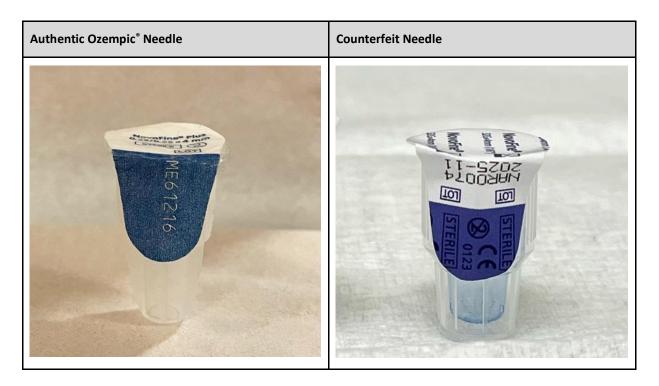
FDA and Novo Nordisk are testing the seized product and do not yet have conclusive information about the drugs' identity, quality, or safety.

Analyses and testing of the product is underway. Visual examination confirms that needles from these samples are counterfeit. Accordingly, Novo Nordisk cannot confirm their sterility, which may present an increased risk of infection for patients who use the counterfeit product. However, additional testing is needed to definitively determine product composition.

Box image featuring the serial and lot number of counterfeit Ozempic® product:



Visuals of authentic and counterfeit needles are shown below:



### **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 couterfeit 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®'

Additional counterfeit components are the labeling on the pen, the accompanying literature, and the carton.

<u>Semaglutide.com</u> is available as a resource hub for US consumers, healthcare providers, and retailers to provide information about responsible use of semaglutide, including how to spot a counterfeit product.

## WHAT TO DO: GUIDANCE FOR RETAILERS AND CONSUMERS

Retail pharmacies are advised to purchase authentic Ozempic\* (semaglutide) injection 1 mg and other semaglutide-containing medicines through <u>authorized distributors of Novo Nordisk</u>. Pharmacies are encouraged to review the photographs and information provided above. If there is concern, please call Novo Nordisk customer care at 1-800-727-6500 Monday through Friday from 8:30 AM to 6:00 PM EST.

Patients are encouraged to only acquire Ozempic\* (semaglutide) injection 1 mg through pharmacies and to check the product before using for any signs of counterfeiting as outlined above.

o If a prescription is filled via a major retailer who uses our authorized distributors, Novo Nordisk believes the risk of receiving counterfeit product is minimized.

- o Patients should check their Ozempic\* box to identify if it reflects lot number in question, NAR0074, and serial number 430834149057.
- o To report suspicious Ozempic® product with serial number 430834149057 or other suspected Novo Nordisk counterfeit products, or if patients need additional help determining if a Novo Nordisk product is counterfeit, please call Novo Nordisk customer care at 1-800-727-6500 Monday through Friday from 8:30 AM to 6:00 PM EST. Patients can also report it directly with OCI here: Report Suspected Criminal Activity (fda.gov).

If an individual is experiencing any side effects that may be related to the use of a counterfeit product, that person should immediately discontinue use and contact their healthcare provider, and is additionally encouraged to report the event to FDA's MedWatch Safety Information and Adverse Event Reporting Program (1-800-FDA-1088 or <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>) as well as to Novo Nordisk, using the same customer care number (1-800-727-6500).

Websites selling counterfeit and/or tampered medicines should be reported to FDA. Suspected counterfeit products may be reported to FDA by calling your local <u>FDA consumer complaint coordinator</u> or by reporting it directly here <u>Report Suspected Criminal Activity (fda.gov)</u>.

#### About Ozempic®

Ozempic® (semaglutide) injection 0.5 mg, 1 mg or 2 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes and to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes with known heart disease.

Ozempic® is a registered trademark of Novo Nordisk A/S.

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