



Subject: Compounded semaglutide products

Dear Health Care Provider,

At Novo Nordisk, patient safety is a top priority. We want to address concerning reports we have received about weight loss clinics, pharmacies, and other companies claiming to have availability of compounded "semaglutide," including products that purport to offer "semaglutide" in fixed-dose combinations with other ingredients. These compounded products do not have the same safety, quality, and effectiveness assurances as approved drugs, and may expose patients to potentially serious health risks.

We want healthcare providers to know that Novo Nordisk does not sell semaglutide for the purposes of compounding with other products and we have not conducted studies to evaluate the safety and effectiveness of semaglutide when compounded with other ingredients. Novo Nordisk is the only company in the United States with FDA-approved products containing semaglutide, identified under the trade names Wegovy[®], Ozempic[®], and RYBELSUS[®], available by prescription only. Practices involving the advertising of compounded "semaglutide" are not condoned by or affiliated with the brands for which Novo Nordisk holds the FDA approval and marketing rights.

Compounded medicines, including "semaglutide", are not approved by the FDA, which means the agency does not verify the safety, effectiveness, or quality of compounded drugs before they are marketed. Furthermore, it is unclear if the facilities responsible for manufacturing such products are registered with the FDA and in compliance with Good Manufacturing Practice (cGMP) requirements.

In some cases, companies are marketing their compounded "semaglutide" products as "generic" versions of semaglutide, which is false and misleading. All generic drugs require approval from the FDA, and it is important to be aware that no FDA-approved generic versions of semaglutide currently exist.

Some entities are marketing their compounded semaglutide as "generic Ozempic[®]" for "weight loss." Ozempic[®] is not indicated for weight management, should not be marketed or prescribed as a weight loss treatment, and is not interchangeable with Wegovy[®]. In addition, some entities are selling compounded "semaglutide" in combination with other ingredients, (including vitamin B6, vitamin B12, and the amino acid L-carnitine, among others), claiming that these additional ingredients increase the effectiveness of semaglutide, mitigate certain possible side effects of semaglutide, and/or provide additional clinical benefits. Semaglutide has not been systematically studied for co-administration with any of these additional ingredients, the safety of such co-administration has not been established, and the claims of additional clinical benefits have not been proven by substantial evidence.

We take our duty to the medical community very seriously and feel a responsibility to keep you informed of this situation.

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Novo Nordisk Inc.

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This letter is not intended as a complete description of the benefits and risks related to the use of Wegovy[®], Ozempic[®], or RYBELSUS[®]. Please refer to the full prescribing information and medication guide.

Reporting Adverse Events

You are encouraged to report negative side effects of compounded prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Reporting False or Misleading Promotion

Healthcare providers who identify potentially false or misleading promotion regarding compounded semaglutide may report such activity to FDA by email to BadAd@fda.gov, by toll-free call to 855-RX-BADAD (855-792-2323), or by writing to:

Bad Ad Program
FDA/CDER/OPDP
5901-B Ammendale Rd
Beltsville, MD 20705-1266

Wegovy[®], Ozempic[®], and RYBELSUS[®]

Wegovy[®] is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m² or greater (obesity), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition.

Ozempic[®] is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

RYBELSUS[®] is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Additional Information

You may contact our Medical Information department at 1-800-727-6500 if you have any questions about the information contained in this letter or the safe and effective use of Wegovy[®], Ozempic[®], or RYBELSUS[®].

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