# FDA Approves First Generic of Liraglutide Injection to Lower Blood Sugar in Patients With Type 2 Diabetes

The approval of the generic to liraglutide injection, currently in shortage, could help increase patient access to the type 2 diabetes treatment.

The FDA announced today the regulatory approval of the first generic referencing liraglutide injection 18 mg/3 ml (Victoza; Nova Nordisk), a glucagon-like peptide-1 (GLP-1) receptor agonist designed to improve glycemic control in adult and pediatric patients 10 years and older with type 2 diabetes (T2D), according to a news release from the FDA.[1]

The approval is indicated as an adjunct to diet and exercise. Liraglutide injection, including other GLP-1 medications such as semaglutide (Ozempic, Wegovy; Novo Nordisk), remain in shortage. The FDA often prioritizes the assessment of generic drugs that are in shortage to help improve patient access.[2,3]


*The approval marks the first generic approved of liraglutide injection.*

"Generic drugs provide additional treatment options which are generally more affordable for patients," said Iilun Murphy, MD, director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research, in the news release. "Today's approval underscores the FDA's continued commitment to advancing patient access to safe, effective and high-quality generic drug products."[1]

Prescribing information for generic liraglutide injection contains a boxed warning that advises health care professionals, pharmacists, and patients of the increased risk of thyroid C-cell tumors. The FDA warns that patients who have had, or have family members who have ever had, medullary thyroid carcinoma should not use liraglutide. Additionally, FDA says that those who have had a prior serious hypersensitivity reaction to liraglutide or any of its product components should not use the medication. Furthermore, patients who have multiple endocrine neoplasia syndrome type 2 should not be administered liraglutide injection.[1]

Further warnings are included, including regarding pancreatitis, liraglutide pen sharing, hypoglycemia, hypersensitivity, and acute gallbladder disease. Common adverse effects reported in clinical trials analyzing liraglutide injection include diarrhea, nausea, vomiting, decreased appetite, and dyspepsia.[1]

"The FDA supports development of complex generic drugs, such as GLP-1s, by funding research and informing industry through guidance as part of our ongoing efforts to increase access to needed medications," Murphy said in the press release.[1]

Millions of people globally are affected by T2D, which has been increasingly diagnosed in children, teens, and young adults, the FDA noted in the press release. Liraglutide creates similar effects in the body as GLP-1 in the pancreas, improving blood sugar levels in patients.[1]

The approval continues the proliferation of GLP-1 products across the health care landscape as they continue to be found effective in myriad indications. As more patients continue to seek out GLP-1s, pharmacists should ensure reliable information is utilized to determine whether a patient may benefit from GLP-1 treatment. Because of the

increased public interest, many of these drugs—including liraglutide—are in shortage; generic drugs in this space can help ease issues related to access during such shortages.[1,4]

## REFERENCES


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