



## Victoza® (liraglutide) – New indication, new warning

- On August 25, 2017, [Novo Nordisk announced](#) the FDA approval of [Victoza \(liraglutide\)](#), to reduce the risk of major adverse cardiovascular (CV) events [CV death, non-fatal myocardial infarction (MI), or non-fatal stroke] in adults with type 2 diabetes mellitus (T2DM) and established CV disease.
  - Previously, Victoza was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
  - Victoza is not a substitute for insulin. Victoza should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
  - The concurrent use of Victoza and prandial insulin has not been studied.
- Approval for the new indication was based on the results from the [LEADER](#) study - a randomized, double-blind, placebo-controlled trial that enrolled 9,340 patients with T2DM at high risk of major adverse CV events. Patients received standard of care plus Victoza (up to 1.8 mg daily) or placebo and were followed for 3.5 – 5 years. The primary endpoint was the first occurrence of a composite CV outcome comprising of CV death, non-fatal MI or non-fatal stroke.
  - The primary outcome occurred in significantly fewer patients in the Victoza group (13.0%) vs. placebo group (14.9%) (HR = 0.87; 95% CI: 0.78, 0.97; p < 0.001 for noninferiority; p = 0.01 for superiority).
- The *Warnings and Precautions* section was also updated with information regarding acute gallbladder disease.
  - In the LEADER trial, 3.1% of Victoza-treated patients vs. 1.9% of placebo-treated patients reported an acute event of gallbladder disease, such as cholelithiasis or cholecystitis. The majority of events required hospitalization or cholecystectomy.
  - If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.
- Victoza carries a boxed warning for risk of thyroid C-cell tumors.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.