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FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications

FDA Evaluation Did Not Identify an Increased Risk of Suicidal Ideation or Behavior With the Use of GLP-1 RA Medications

This information is an update to the FDA Drug Safety Communication: Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity issued on January 30, 2024.

What Is FDA Doing?

FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications that currently include such language. The affected products are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide). This action follows a comprehensive FDA review that found no increased risk of SI/B associated with the use of GLP-1 RA medications.

Saxenda, Wegovy, and Zepbound are each approved for weight reduction in persons with obesity or overweight. At the time of the original FDA approvals, the labeling for each of these products included information in the *Warnings and Precautions* section about the potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss.

Labeling for GLP-1 RA medications that are approved to improve glycemic (blood sugar) control or other complications in patients with type 2 diabetes mellitus does not currently include information on the risk of SI/B. Today's FDA action will ensure consistent messaging across the labeling for all FDA-approved GLP-1 RA medications.

What Are GLP-1 RAs?

GLP-1 RAs are a class of medicines that mimic the effects of a natural hormone called glucagon-like peptide-1 (GLP-1) that is released by the intestine. GLP-1 helps lower blood glucose (sugar) levels after eating and acts in parts of the brain that control appetite and food intake. FDA approved the first GLP-1 RA as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus in 2005. There are now several medications in this drug class on the market.

What Should Patients and Caregivers Do?

Patients and caregivers should be aware that, after a comprehensive review, FDA found no increased risk of SI/B with the use of GLP-1 RA medications. Patients should continue taking their medication as prescribed and discuss any concerns with their health care professionals.

Suicidal ideation occurs when a person is thinking, considering, or planning suicide. Suicidal behavior occurs when a person takes physical actions toward suicide, including suicide attempts or completed suicide (an act of self-harm that causes death). Tell your health care professional if you experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Call or text 988 or go to the website at https://988lifeline.org/, which provides free support for people in distress 24 hours a day, 7 days a week.

What Should Health Care Professionals Do?

Health care professionals should be aware that FDA found no increased risk of SI/B with the use of GLP-1 RA medications and is requesting the removal of this Warning and Precaution from the prescribing information for the GLP-1 RA medications (Saxenda, Wegovy, and Zepbound) that include such language. Health care professionals should be prepared to discuss with patients that FDA has found no increased risk after conducting a comprehensive review of the available data.

If individuals disclose that they are experiencing SI/B, refer them to mental health professionals for evaluation.

What Did FDA Find?

The labeling of GLP-1 RA medications approved for weight reduction in persons with obesity or overweight contains information in the *Warnings and Precautions* section regarding a potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss.

In July 2023, after receiving postmarketing reports of SI/B in patients taking GLP-1 RA medications, FDA initiated further investigation of the potential risk of SI/B for GLP-1 RA medications. FDA performed a preliminary review of clinical trial and postmarketing data, including observational studies and case reports, and publicly reported those findings in its January 2024 Drug Safety Communication.

The initial review of GLP-1 RA clinical trial data did not find an association between the use of GLP-1 RAs and the occurrence of SI/B. However, because of the small number of cases of SI/B observed in individual trials, there was considerable uncertainty in the risk estimate. To address this concern, FDA performed a comprehensive meta-analysis of clinical trials across GLP-1 RA drug development programs to improve the precision of the risk estimate. The meta-analysis assessed the risk of SI/B comparing GLP-1 RA medications to placebo. There were 91 placebo-controlled GLP-1 RA medication trials in the meta-analysis that included 107,910 patients (60,338 treated with a GLP-1 RA and 47,572 treated with placebo). The results did not show an increased risk for SI/B or for other relevant psychiatric adverse events such as anxiety, depression, irritability, or psychosis.

In addition, FDA conducted a retrospective cohort study using administrative healthcare claims data from the FDA Sentinel System to compare the risk of intentional self-harm between new users of GLP-1 RAs and sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with type 2 diabetes mellitus.

The study population included 2,243,138 users (1,161,983 initiated on a GLP-1 RA and 1,081,155 initiated on a SGLT2i) from 10 data partners during the period between October 1, 2015, and September 20, 2023. After controlling for baseline confounders in the study, FDA did not find an increased risk of intentional self-harm in GLP-1 RA users compared to SGLT2i users. Similarly, FDA did not find an increased risk in the subgroup of patients with both type 2 diabetes mellitus and obesity.

FDA also reviewed published observational and pooled studies evaluating the relationship between GLP-1 RAs and SI/B, and related outcomes. Our review concluded that the totality of these studies does not support a causal relationship between the use of GLP-1 RAs and the occurrence of SI/B.

Therefore, consistent with these findings, FDA is requesting that application holders remove information regarding the risk of SI/B from the labeling of GLP-1 RA medications that currently include such language.

How Do I Report Side Effects from GLP-1 RAs?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving GLP-1 RAs or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

How Can I Get New Safety Information on Medicines I'm Prescribing or Taking?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving GLP-1 RAs or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

Contact FDA
For More Info
855-543-DRUG (3784) and press 4
druginfo@fda.hhs.gov

Report a Serious Problem to MedWatch
Complete and submit the report Online.
Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.