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

Preliminary evaluation does not suggest a causal link

01-11-2024 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) has been evaluating reports of suicidal thoughts or actions in patients treated with a class of medicines called glucagon-like peptide-1 receptor agonists (GLP-1 RAs; see the list in Table 1 below). These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. Our preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions.

Over the last several months, we have conducted detailed reviews of reports of suicidal thoughts or actions received in the FDA Adverse Event Reporting System (FAERS). Because the information provided was often limited and because these events can be influenced by other potential factors, we determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 RAs. Similarly, our reviews of the clinical trials, including large outcome studies and observational studies, did not find an association between use of GLP-1 RAs and the occurrence of suicidal thoughts or actions. However, because of the small number of suicidal thoughts or actions observed in both people using GLP-1 RAs and in the comparative control groups, we cannot definitively rule out that a small risk may exist; therefore, FDA is continuing to look into this issue.

Additional evaluations include a meta-analysis of clinical trials across all GLP-1 RA products and an analysis of postmarketing data in the Sentinel System. A meta-analysis is a large, combined analysis of findings from clinical trials. Sentinel is a very large data network that contains health insurance claims and patient health records that can be used to investigate safety questions about FDA-regulated products. We will communicate our final conclusions and recommendations after we complete our review or have more information to share.

Patients should not stop taking GLP-1 RAs without first consulting your health care professional, as stopping these medicines may worsen your condition. Talk to your health care professional if you have questions or concerns. 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.

The current prescribing information for the GLP-1 RAs approved to treat patients with obesity or overweight contains information about the risk of suicidal thoughts and actions. This information is also included in the labels of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or tested for weight loss.

Consistent with the prescribing information for these medications, **health care professionals** should monitor for and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Health care professionals should consult the prescribing information when treating patients with these medications.

GLP-1 RAs are a class of several medicines (see list in Table 1) used to improve blood sugar (glucose) control and reduce the risk of heart disease in patients with type 2 diabetes. Some of these medicines are also used to help patients with obesity or overweight to lose weight. FDA approved the first GLP-1 RA in 2005, and there are now several in this class. GLP-1 RAs work by mimicking a hormone in the intestines called GLP-1 to stimulate the release of insulin and reduce blood glucose after eating a meal. These medicines also slow down food traveling through the digestive tract, which can help make someone feel full longer. GLP-1 receptors are also present in parts of the brain that regulate appetite.

Table 1. FDA-Approved GLP-1 RAs

Trade name	Generic name	Population (indication)	Approval year
Byetta	exenatide	Type 2 diabetes	2005
Victoza	liraglutide	Type 2 diabetes	2010
Trulicity	dulaglutide	Type 2 diabetes	2014
Saxenda	liraglutide	Obesity/overweight	2014
Adlyxin	lixisenatide	Type 2 diabetes	2016
Xultophy	liraglutide + insulin degludec	Type 2 diabetes	2016
Soliqua	lixisenatide + insulin glargine	Type 2 diabetes	2016
Bydureon BCise	exenatide	Type 2 diabetes	2017
Ozempic	semaglutide	Type 2 diabetes	2017
Rybelsus	semaglutide	Type 2 diabetes	2019
Wegovy	semaglutide	Obesity/overweight	2021
Mounjaro	tirzepatide**	Type 2 diabetes	2022
Zepbound	tirzepatide**	Obesity/overweight	2023

**Tirzepatide is a dual gastric inhibitory polypeptide (GIP) receptor and GLP-1 RA.

We encourage health care professionals and patients 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 the page.

Health care professionals, patients, and consumers can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Related Information

- Diabetes Medicines
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines