

FDA evaluates reports of suicidal thoughts or actions in patients taking glucagonlike peptide-1 receptor agonists (GLP-1 RAs)

- On January 11, 2024, the <u>FDA announced</u> results from a preliminary evaluation did not show a causal link between suicidal thoughts or actions in patients treated with GLP-1 RAs.
- GLP-1 RAs are a class of medicines used to improve blood sugar 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. A complete list of GLP-1 agonists can be found here.
- The FDA conducted detailed reviews of reports of suicidal thoughts or actions received in the FDA Adverse Event Reporting System. The information in these reports was limited and potentially influenced by other factors. The FDA determined that the information did not demonstrate a clear relationship with the use of GLP-1 RAs.
- Similarly, the FDA 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, the FDA cannot definitively rule out that
 a small risk may exist; therefore, the 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.
- Patients should not stop taking GLP-1 RAs without first consulting their healthcare provider.
 Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using GLP-1 RAs.
- Patients should talk to their health care provider if they experience any new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Call or text 988 or visit https://988lifeline.org/, which provides free support for people in distress 24 hours a day, 7 days a week.
- Current prescribing information for GLP-1 RAs approved to treat patients with obesity or
 overweight conditions contains information about the risk of suicidal thoughts and actions. This
 information is included in the labels of other types of weight loss drugs and is based on reports of
 adverse events observed from a variety of older medicines used for weight loss.

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