Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-003-CG
January 15, 2024

FDA announced that Certain Type of Medicines Approved for Type 2 Diabetes and Obesity: Drug Safety Communication - Update on FDA's Ongoing Evaluation of Reports of Suicidal Thoughts or Actions.

RECOMMENDATIONS

1. Patients

a. You should not stop taking GLP-1 RAs without first consulting your health care professional, as stopping these medicines may worsen your condition.

b. Talk to your health care professional if you have questions or concerns.

c. Tell your health care professional if you experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.

d. 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.

2. Health Care Professionals

a. 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.

b. Health care professionals should consult the prescribing information when treating patients with these medications.

3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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FDA U.S. FOOD & DRUG ADMINISTRATION

Certain Type of Medicines Approved for Type 2 Diabetes and Obesity: Drug Safety Communication - Update on FDA's Ongoing Evaluation of Reports of Suicidal Thoughts or Actions

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[Posted 01/11/2024]

AUDIENCE: Patient, Health Professional, Endocrinology, Pharmacy

ISSUE: The 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. These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. FDA's preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions.

Over the last several months, the FDA has 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, the FDA determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 RAs. Similarly, the FDA's 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. 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. The FDA will communicate final conclusions and recommendations after completion of the review or when there is more information to share.

BACKGROUND:

- GLP-1 RAs are a class of several medicines 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.

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Health Care Professionals

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- Health care professionals should consult the prescribing information when treating patients with these medications.

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.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- 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 form, or submit by fax to 1-800-FDA-0178.

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