COMMUNICATION

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URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

01/11/2024

Drug Indication:

Type 2 Diabetes and Obesity

Safety Topic:

FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking glucagon-like peptide-1 (GLP-1) receptor agonists approved for type 2 diabetes and obesity.

Evaluation of Suicidal Thoughts with Type 2 Diabetes and Obesity Drugs

It is for this reason that we are notifying you that on 01/11/2024 the U.S. Food and Drug Administration (FDA) published a safety communication for the following class of medicine: glucagon-like peptide-1 receptor agonists.

Reason for Communication:

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

Even though the preliminary evaluation does not suggest a causal link, the FDA is continuing to investigate this issue since they cannot completely rule out that a small risk may exist.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients should seek immediate medical attention if they experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252 ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:

1. U.S. Food and Drug Administration. (2024). Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicine approved for type 2 diabetes and obesity. https://www.fda.gov/media/175358/download?attachment
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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