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:

01/19/2024

Drug Indication:

Osteoporosis

Safety Topic:

FDA adds a Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking Prolia (denosumab). Patients on dialysis or with mineral and bone disorder at highest risk.

New Boxed Warning for Prolia regarding Severe Hypocalcemia

It is for this reason that we are notifying you that on 01/19/2024 the U.S. Food and Drug Administration (FDA) published a safety communication for the following medication: Prolia (denosumab).

Reason for Communication:

The FDA has reviewed available information and has concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization and death. As a result, the prescribing information now includes this new *Boxed Warning*.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. For patients with advanced CKD (especially those on dialysis) already taking Prolia, frequent monitoring of calcium in the blood, especially for the first 2 to 10 weeks after each Prolia injection, is recommended.

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). FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab). https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease
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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