COMMUNICATION

COM-2022-069

07
DECEMBER
2022

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:

11/22/2022

Safety Topic:

Risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia™ (denosumab)

Drug Indication:

Prolia™ (denosumab) is indicated for: [1] treatment of postmenopausal women with osteoporosis at high risk for fracture, [2] treatment to increase bone mass in men with osteoporosis, [3] treatment of glucocorticoid-induced osteoporosis, [4] treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer, [5] treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

Risk of Severe Hypocalcemia with Prolia™.

It is for this reason that we are notifying you that on 11/22/2022 the US Food and Drug Administration (FDA) published a safety communication for the following product(s): Prolia™ (denosumab).

Reason for Communication:

The FDA has reviewed the interim results from an ongoing safety study of Prolia™. The interim results suggest an increased risk of hypocalcemia in patients with advanced kidney disease. The FDA has preliminary results from a separate internal study further investigating hypocalcemia in dialysis patients treated with Prolia™ and the results show a substantial risk with serious outcomes, including hospitalization and death.

The FDA is alerting health care professionals and patients about the seriousness of these risks, and they will continue to evaluate this potential safety issue with Prolia™ use in patients with advanced kidney disease, particularly those on dialysis.

The FDA is advising that adequate calcium and vitamin D supplementation and frequent blood calcium monitoring, possible more often than is already being conducted, may help decrease the likelihood or severity of these risks. The FDA suggests that healthcare professionals' direct patients on dialysis to immediately seek medical attention if they experience symptoms of hypocalcemia. The FDA will communicate its final conclusions and recommendations when it has completed its review.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider.

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- Clinical Department. Our pharmacists will help you.

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

PharmPix Drug Safety Communication Number COM-2022-069 DECEMBER 2022

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REFERENCES

1. U.S. Food and Drug Administration. (2022, November 22). *FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab)*. https://www.fda.gov/drugs/drug-safety-and-availability/fda-investigating-risk-severe-hypocalcemia-patients-dialysis-receiving-osteoporosis-medicine-prolia
2. Amgen. (2022). Prolia (denosumab). [Full Prescribing Information]. U.S. Food & Drug Administration Drugs@FDA Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125320s210lbl.pdf