October 2019

IMPORTANT DRUG WARNING

Subject: Potential of carton confusion between UDENYCA® and Prolia® packaging associated with the risk of administration or dispensing error and adverse events

Dear Health Care Provider,

The purpose of this letter is to make you aware of the potential of carton confusion between the UDENYCA® (pegfilgrastim-cbqv) and Prolia® (denosumab) packaging which could lead to a risk of product administration or dispensing error and adverse events.

Potential of carton confusion between UDENYCA® and Prolia®

UDENYCA® and Prolia® have a similar carton appearance (Figure 1) which has led to product administration or dispensing errors and adverse events.

1. Carton Appearance: Both cartons look similar with a green/white color scheme and green horizontal bands across the top (Figure 1).
2. Presentation and Strength: Both cartons hold one single-dose prefilled syringe, and both medications are intended for subcutaneous administration. The UDENYCA® syringe contains 6 mg and the Prolia® syringe contains 60 mg.
   a. The needle guard of UDENYCA® syringe is colorless while the Prolia® syringe is translucent green (Figure 2).
3. Storage: Both are refrigerated items and have the potential to be stored next to each other.

Figure 1: UDENYCA® (left) and Prolia® (right) Cartons

Figure 2: UDENYCA® (left) and Prolia® (right) Syringes
Adverse Events:
To date, Coherus has received two reports of patients who received UDENYCA® (pegfilgrastim-cbzv) instead of the intended Prolia® (denosumab). One patient experienced non-serious bone pain and the other patient was hospitalized with increased white blood cells, chest pain, and myocardial infarction (non-STEMI). Both cases occurred due to personnel errors and failure to follow the dosing protocol in the clinical setting.

Prescriber Action:
1. Pharmacy staff should be made aware of the similar carton appearance between UDENYCA® and Prolia®.
2. Health care providers and pharmacy staff are encouraged to store UDENYCA® and Prolia® inventories in separate areas away from one another.
3. Follow institutional protocol such as barcode verification, review of the label/name on the carton, and good documentation practices before dispensing and administering these drugs.

Reporting Adverse Events:
Health care providers and patients are encouraged to report adverse events, events of carton confusion, and administration error to Coherus BioSciences Medical Information at 1-800-483-3692. You are also encouraged to report adverse events to the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch.

Contact Coherus BioSciences Medical Information department at 1-800-4UDENYCA (1-800-483-3692) if you have any questions about the information contained in this letter or the safe and effective use of UDENYCA®. Please see enclosed full prescribing information. For additional product information, please visit UDENYCA.com.

Sincerely,

[Signature]
Head of Medical Affairs

Enclosure:
(1) UDENYCA® Full Prescribing Information

UDENYCA is a registered trademark of Coherus BioSciences, Inc.
Prolia is a registered trademark of Amgen Inc.
©2019 Coherus BioSciences, Inc. All rights reserved.